DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 417, 476, 480, 484, and 495

[CMS–1735–F]

RIN 0938–AU11

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2021 and to implement certain recent legislation. We are also making changes relating to Medicare graduate medical education (GME) for teaching hospitals. In addition, we are providing the market basket update that will apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis, subject to these limits for FY 2021. We are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2021. In this FY 2021 IPPS/LTCH PPS final rule, we are finalizing changes to the new technology add-on payment pathway for certain antimicrobial products and other changes to new technology add-on payment policies, and the collection of market-based rate information on the Medicare cost report for cost reporting periods ending on or after January 1, 2021 and finalizing the adoption of a market-based MS–DRG relative weight methodology beginning in FY 2024. We are establishing new requirements or revising existing requirements for quality reporting by acute care hospitals and PPS-exempt cancer hospitals. We also established new requirements and revised existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid Promoting Interoperability Programs. We are also establishing performance standards for the Hospital Value-Based Purchasing (VBP) Program, and updating policies for the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition (HAC) Reduction Program.

DATES:

Effective date: This final rule is effective October 1, 2020.

Applicability dates: The amendments at § 413.89(b)(1)(i), (c)(1), (e)(2)(i)(A)(*2*) are applicable to cost reporting periods before October 1, 2020. The amendments at § 413.89(e)(2)(i)(A)(*1*), (*4*) through (*6*), (i)(B), (iii), and (f) are applicable to cost reporting periods before, on, and after October 1, 2020. The amendments at § 413.89(b)(1)(ii), (c)(2), (e)(2)(i)(A)(*3*) and (e)(2)(ii) are applicable to cost reporting periods beginning on or after October 1, 2020.

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SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the internet at: *http://www.gpo.gov/fdsys.*

Tables Available Through the Internet on the CMS Website

The IPPS tables for this FY 2021 final rule are available through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, ''FY 2021 IPPS Final rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for

this FY 2021 final rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1735–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this FY 2021 IPPS/LTCH PPS final rule. Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel at (410) 786–4552.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2021 IPPS/LTCH PPS final rule makes payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This final rule also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2021 final rule, we are continuing policies to address wage index disparities impacting low wage index hospitals; and including policies related to new technology add-on payments for certain antimicrobial products, other policies related to new technology add-on payments, collecting market-based rate information on the Medicare cost report for cost reporting periods ending on or after January 1, 2021, and finalizing the adoption of a market-based MS–DRG relative weight methodology beginning in FY 2024.

We are establishing new requirements and revising existing requirements for quality reporting by acute care hospitals and PPS-exempt cancer hospitals that participate in Medicare. We are also establishing new requirements and revising existing requirements for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

We are establishing performance standards for the Hospital Value-Based Purchasing (VBP) Program and updating policies for the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition (HAC) Reduction Program.

Under various statutory authorities, we either discuss continued program implementation or are making changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2021 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.

• Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.

• Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

• Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.

• Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.

2. Waiver of the 60-day Delayed Effective Date for the Final Rule

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS-CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

Due to the significant devotion of resources to the COVID–19 response, for the reasons discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32889 through 32890) and as also discussed in section XI.D. of the preamble of this final rule, we are hereby waiving the 60-day delay in the effective date of the final rule.

3. Summary of the Major Provisions

The following is a summary of the major provisions in this final rule. In general, these major provisions are part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the proposed changes that were included in the FY 2021 IPPS/LTCH PPS proposed rule is presented in section I.D. of the preamble of this final rule.

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110 90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2021, we are making an adjustment of + 0.5 percent to the standardized amount.

b. Changes to the New Technology Add-On Payment Policy for Certain Antimicrobial Products

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297), we established an alternative inpatient new technology add-on payment pathway for certain antimicrobial products in light of the significant concerns related to the ongoing public health crisis represented by antimicrobial resistance. Under this alternative pathway, if a medical product receives the FDA's Qualified Infectious Disease Product (QIDP) designation and received FDA marketing authorization, such a product will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

In the proposed rule, in light of recent information that continues to highlight the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance of this issue both with respect to Medicare beneficiaries and public health overall, we proposed changes to the new technology add-on payment policy for certain antimicrobials for FY 2021.

As discussed in section II.G.9.b. of the preamble of this final rule, after consideration of public comments, we are finalizing our proposal to expand our alternative new technology add-on payment pathway for QIDPs to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). Under this policy, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial product is approved through FDA's LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

Under current policy, a new technology must receive FDA marketing authorization (for example, approval or clearance) by July 1 to be considered in the final rule in order to allow complete review and consideration of all the information to determine if the technology meets the new technology add-on payment criteria. For the reasons discussed in section II.G.9.c. of the preamble of this final rule, after consideration of public comments, we are finalizing our proposal to provide for conditional new technology add-on payment approval for products designated as QIDPs that do not receive FDA approval by July 1 and products that do not receive approval through FDA's LPAD pathway by July 1 but otherwise meet the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

c. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low hospitals, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332), we adopted a policy to provide an opportunity for certain low wage index hospitals to increase employee compensation by increasing the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, for FY 2021, we are continuing the low wage index hospital policy, and also applying this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

d. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this final rule, we have updated our estimates of the three factors used to determine uncompensated care payments for FY 2021. We continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2; however, given the unprecedented effects on health insurance enrollment as a result of the public health emergency for the COVID–19 pandemic, OACT has updated the NHEA-based projection of the FY 2021 rate of uninsurance using more recently available unemployment data. In addition, we are using a single year of data on uncompensated care costs from Worksheet S–10 of the FY 2017 cost reports to calculate Factor 3 in the FY 2021 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. For IHS and Tribal hospitals and Puerto Rico hospitals we are continuing to use the low-income insured days proxy to calculate Factor 3 for these hospitals. Furthermore, we are establishing that to calculate Factor 3 for FY 2022 and all subsequent fiscal years for all eligible hospitals, except IHS and Tribal hospitals and Puerto Rico hospitals, we will use the most recent available single year of audited Worksheet S–10 data. We are also making other methodological changes for purposes of calculating Factor 3.

e. Reduction of Hospital Payments for Excess Readmissions

We are finalizing our proposal to make changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. In this FY 2021 IPPS/LTCH PPS final rule, we are finalizing the following policies: (1) To automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary; and (2) to update the definition of *applicable period* at 42 CFR 412.152 to align with this policy.

f. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this FY 2021 IPPS/LTCH PPS final rule, we are providing newly established performance standards for certain measures for the FY 2023 program year, the FY 2024 program year, the FY 2025 program year, and the FY 2026 program year.

h. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals, effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to hospitals that rank in the worst-performing quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this FY 2021 IPPS/LTCH PPS final rule, we are finalizing the following policies: (1) To automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the secretary, (2) to make refinements to the process for validation of HAC Reduction Program measure data in alignment with the Hospital IQR Program measure validation policies finalized in this rule; and (3) to update the definition of *applicable period* at 42 CFR 412.170 to

align with the policy to automatically adopt applicable periods.

g. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year.

In this FY 2021 IPPS/LTCH PPS final rule, we are finalizing proposals related to the reporting, submission, and public display requirements for eCQMs. These policies are: (1) Progressively increasing the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a three-year period, by requiring hospitals to report: (a) Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination; (b) three quarters of data for the CY 2022 reporting period/FY 2024 payment determination; and (c) four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years, while continuing to allow hospitals to report: (i) Three self-selected eCQMs, and (ii) the Safe Use of Opioids eCQM; and (2) beginning public display of eCQM data starting with data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. The eCQM-related policies are in alignment with proposals under the Promoting Interoperability Program. We also are finalizing our proposal to expand the requirement to use EHR technology certified to the 2015 Edition for submitting data on not only the previously finalized Hybrid Hospital-Wide Readmission measure, but all hybrid measures in the Hospital IQR Program.

We also are finalizing proposals to streamline the validation processes under the Hospital IQR Program. We are finalizing proposals to: (1) Update the quarters of data required for validation for both chart-abstracted measures and eCQMs; (2) expand targeting criteria to include hospital selection for eCQMs; (3) change the validation pool from 800 hospitals to 400 hospitals; (4) remove the current exclusions for eCQM validation selection, (5) require electronic file submissions for chart-abstracted measure data; (6) align the eCQM and chart-abstracted measure scoring processes; and (7) update the educational review process to address eCQM validation results.

h. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In this FY 2021 IPPS/LTCH PPS final rule, we are finalizing our proposal to refine two existing program measures, Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138) and Central Line-associated Bloodstream Infection (CLABSI) (NQF #0139), to adopt the updated SIR calculation methodology developed by the Center for Disease Control and Prevention's (CDC) that calculates rates using updated HAI baseline data that are further stratified by patient location.

i. Medicare and Medicaid Promoting Interoperability Programs

For purposes of an increased level of stability, reducing the burden on eligible hospitals and CAHs, and clarifying certain existing policies, we are finalizing several changes to the Medicare Promoting Interoperability Program. Specifically, these policies include: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; (3) to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; (4) to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a three year period. Specifically, we finalized proposals to require: (a) Two self-selected calendar quarters of data for the CY 2021 reporting period; (b) three self-selected calendar quarters of data for the CY 2022 reporting period; and (c) four calendar quarters of data beginning with the CY 2023 reporting period, where the submission period for the Medicare Promoting Interoperability Program will be the 2 months following the close of the respective calendar year; (5) to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021 on the *Hospital Compare* and/or *data.medicare.gov* websites or successor websites; (6) to correct errors and amend regulation text under § 495.104(c)(5)(viii)(B) through (D) regarding transition factors under section 1886(n)(2)(E)(i) for the incentive payments for Puerto Rico eligible hospitals; and (7) to correct errors and amend regulation text under §§ 495.20(e)(5)(iii) and (l)(11)(ii)(C)(1) for regulatory citations for the Office of the National Coordinator for Health Information Technology (ONC) certification criteria. We are amending our regulation texts as necessary to incorporate these finalized changes.

j. Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights

As discussed in section IV.P. of the preamble of this final rule, in order to reduce the Medicare program's reliance on the hospital chargemaster and to support the development of a market-based approach to payment under the Medicare FFS system, we are finalizing our proposal, with modification, to require that hospitals report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021.

Specifically, we are finalizing that hospitals would report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations (also referred to as MA organizations) payers, by MS–DRG. The market-based rate information we are finalizing for collection on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, as described previously, for a hospital's MA organization payers. The payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency Final Rule (84 FR 65524) that can be cross-walked to an MS–DRG. We believe that because hospitals are already required to publically report payer-specific negotiated charges, in accordance with the Hospital Price Transparency Final Rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

We are also finalizing the market-based MS–DRG relative weight methodology as described in the FY

2021 IPPS/LTCH PPS proposed rule, which would incorporate this market-based rate information, beginning in FY 2024.

4. Summary of Costs and Benefits

• *Adjustment for MS–DRG Documentation and Coding Changes.* Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2021, we are making an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.

• *Changes to the New Technology Add-On Payment Policy for Certain Antimicrobial Products.* In light of recent information that continues to highlight the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance of this issue both with respect to Medicare beneficiaries and public health overall, in this final rule we are making changes to the new technology add-on payment policy for certain antimicrobials for FY 2021. We are expanding our alternative new technology add-on payment pathway for QIDPs to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). Under this policy, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial product is approved through FDA's LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

We are also providing for conditional new technology add-on payment approval for products designated as QIDPs that do not receive FDA approval by July 1 and products that do not receive approval through FDA's LPAD pathway by July 1 (the current deadline for consideration in the final rule) but otherwise meet the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

Given the relatively recent introduction of the FDA's LPAD pathway there have not been any drugs that were approved under the FDA's LPAD pathway that applied for a new technology add-on payment under the IPPS. If all of the future LPADs that would have applied for new technology add-on payments would have been approved under existing criteria, this finalized policy has no impact relative to current policy. To the extent that there are future LPADs that are the subject of applications for new technology add-on payments, and those applications would have been denied under the current new technology add-on payment criteria, this final policy is a cost, but that cost is not estimable. Therefore, it is not possible to quantify the impact of these policies.

• *Wage Index Disparities Between High and Low Wage Index Hospitals.* As discussed in section III.G.3. of the preamble of this final rule, we are continuing to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and applying a budget neutrality adjustment to the standardized amount so that increase is implemented in a budget neutral manner.

• *Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care.* For FY 2021, we are updating our estimates of the three factors used to determine uncompensated care payments. To calculate Factor 2, we are using uninsured estimates produced by OACT as part of the development of the NHEA in conjunction with more recently available data that take into consideration the effects of COVID–19. We are using a single year of data on uncompensated care costs from Worksheet S–10 for FY 2017 to determine Factor 3 for FY 2021 for all hospitals with the exception of Puerto Rico hospitals and Indian Health Service and Tribal hospitals. To determine the amount of uncompensated care for purposes of calculating Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are continuing to use only data regarding low-income insured days for FY 2013. We project that the amount available to distribute as payments for uncompensated care for FY 2021 will decrease by approximately $60 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2020. The uncompensated care payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.

• *Update to the LTCH PPS Payment Rates and Other Payment Policies.* Based on the best available data for the 363 LTCHs in our database, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum to this final rule, which reflect the end of the transition of the statutory application of the site neutral payment rate and the update to the LTCH PPS standard Federal payment rate for FY 2021, would result in an estimated decrease in payments in FY 2021 of approximately $40 million.

• *Changes to the Hospital Readmissions Reduction Program.* For FY 2021 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. We estimate that 2,545 hospitals will have their base operating DRG payments reduced by their FY 2021 hospital-specific payment adjustment factors. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $553 million in FY 2021.

• *Value-Based Incentive Payments under the Hospital VBP Program.* We estimate that there will be no net financial impact to participating hospitals under the Hospital VBP Program for the FY 2021 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2021 program year and, therefore, the estimated amount available for value-based incentive payments for FY

2021 discharges is approximately $1.9 billion.

• *Changes to the HAC Reduction Program.* A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year depend on several different factors. We are making no changes to the scoring methodology, which will continue to use the Winsorized z-score and equal measure weights approaches to determine the worst-performing quartile of hospitals. Any significant impact due to the HAC Reduction Program changes for FY 2021, including which hospitals will receive the adjustment, will depend on the actual experience of hospitals in the Program.

• *Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we estimate that our changes for the Hospital IQR Program in this final rule would result in a total information collection burden increase of 6,533 hours associated with our policies and updated burden estimates and a total cost increase of approximately $253,480, across a four-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination, compared to our previously approved information collection burden estimates.

• *Changes to the Medicare and Medicaid Promoting Interoperability Programs.* With these finalized proposals, we do not estimate any net change in burden hours or total cost for the Medicare Promoting Interoperability Program for CY 2021, given that there are no substantive change in current measures or data requirements for eligible hospitals and CAHs that would affect previously-approved burden. Unrelated to any of this rule's Promoting Interoperability changes, an alteration to the annual information collection's total cost is due to utilizing an updated hourly wage rate for the necessary hospital staff involved in attesting to the objectives and measures under 42 CFR 495.24(e). The Bureau of Labor Statistics (BLS) recently released a 2018 wage rate which, compared to the 2017 rates used in FY 2020 IPPS/LTCH PPS final rule, result in an estimated increase of $24,073 for the annual information collection burden (total cost) in FY 2021. Therefore, multiplying the total annual burden of 21,4950 hours by the 2018 BLS labor cost of $69.34, we estimate the Promoting Interoperability Program's total cost to be $1,487,343 for the CY 2021 EHR reporting period (21,450 hours × $69.34).

• *Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights.* In section IV.P.4. of the preamble of this final rule, we are finalizing a methodology for estimating the MS–DRG relative weights beginning in FY 2024 which utilizes the median payer-specific negotiated charge information we are finalizing to collect on the Medicare cost report. We estimate total annual burden hours for this data collection are as follows: 3,189 hospitals times 20 hours per hospital equals 63,780 annual burden hours and $4,315,993. We refer readers to section XI.B.11. of the preamble of this final rule for further analysis of this assessment.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment for fiscal years beginning on or after October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of

hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Implemented in This Final Rule

1. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). We did not make proposals or updates to the LTCH Quality Reporting Program. We are continuing to maintain portions of section 1899B of the Act, as added by section 2(a) of the IMPACT Act, which, in part, requires LTCHs, among other post-acute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

2. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5

percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

3. Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94)

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) provides that, effective for cost reporting periods beginning on or after October 1, 2020, payment to a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and that the Secretary shall specify the items included in such hematopoietic stem cell acquisition in rulemaking. This statutory provision also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner.

D. Issuance of Notice of Proposed Rulemaking

In the FY 2021 IPPS/LTCH PPS proposed rule that appeared in the May 29, 2020 **Federal Register** (84 FR 32460), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2021 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2021.

The following is a general summary of the changes that we proposed to make.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2021.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2021 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2021 status of new technologies approved for add-on payments for FY 2020, a presentation of our evaluation and analysis of the FY 2021 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2021 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- Proposed revision to the new technology add-on payment policy where the coding associated with an application for new technology add-on payments or a previously approved technology that may continue to receive new technology add-on payments is proposed to be assigned to a proposed new MS–DRG.
- Proposed changes to the timing of the IPPS new technology add-on payment for certain antimicrobial products, and proposed expansion of the alternative pathway for certain antimicrobial products.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of the proposed rule we proposed to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed included, but were not limited to, the following:

- Proposed changes in the labor market area delineations based on revisions to the OMB Core Based Statistical Area (CBSA) delineations and proposed policies related to the proposed changes in CBSAs.
- The proposed FY 2021 wage index update using wage data from cost reporting periods beginning in FY 2017.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2021 based on the 2016 Occupational Mix Survey.
- Proposed application of the rural floor and the frontier State floor, and continuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed change to Lugar county assignments.
- Proposed adjustment to the wage index for acute care hospitals for FY 2021 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the proposed FY 2021 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section IV of the preamble of the proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed changes to MS–DRGs subject to the post-acute care transfer policy and special payment policy.
- Proposed inpatient hospital update for FY 2021.
- Proposed amendment to address short cost reporting periods during applicable timeframe for establishment of service area for SCHs.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status, and proposed amendment for hospital cost reporting periods that are longer or shorter than 12 months.
- The statutorily required IME adjustment factor for FY 2021.
- Proposed changes to the methodology for determining Medicare DSH for uncompensated care payments.
- Proposed changes to payment for allogeneic hematopoietic stem cell acquisition costs.
- Proposed payment adjustment for chimeric antigen receptor (CAR) T-cell therapy clinical trial cases.
- Proposed requirements for payment adjustments under the Hospital Readmissions Reduction Program for FY 2021.
- The provision of estimated and newly established performance standards for the calculation of value-based incentive payments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2021.
- Proposed policy changes related to medical residents affected by residency program or teaching hospital closure.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2021.
- Proposal to collect market-based rate information on the Medicare cost

report for cost reporting periods ending on or after January 1, 2021, and request for comment on a potential market-based MS–DRG relative weight methodology beginning in FY 2024, that we stated we may adopt in this rulemaking.

4. Proposed FY 2021 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to the proposed rule, we discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2021.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of the proposed rule, we discussed—

- Proposed changes to payments to certain excluded hospitals for FY 2021.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of the proposed rule, we set forth—

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2021.
- Proposed rebasing and revising of the LTCH PPS market basket.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the proposed rule, we addressed—

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

8. Other Proposed Changes

Section IX. of the preamble to the proposed rule included the following:

- Proposed changes pertaining to the submission format requirements and reimbursement rates for patient records sent to the Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs).
- Proposed changes pertaining to allowing for mandatory electronic filing of Provider Reimbursement Review Board appeals.
- Proposed changes pertaining to and codification of certain longstanding Medicare Bad Debt policies.

9. Other Provisions of the Proposed Rule

Section X. of the preamble to the proposed rule included our discussion of the MedPAC Recommendations.

Section XI. of the preamble to the proposed rule included the following:

- A descriptive listing of the public use files associated with the proposed rule.
- The collection of information requirements for entities based on our proposals.
- Information regarding our responses to public comments.
- Waiver of the 60-day delay in effective date for the final rule.

10. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to the proposed rule, we set forth the proposed changes to the amounts and factors for determining the proposed FY 2021 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to the proposed rule, we addressed the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2021 for certain hospitals excluded from the IPPS.

11. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2021 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2021. We proposed to establish the adjustment for wage levels, including the proposed changes in the CBSAs based on revisions to the OMB labor market area delineations and a proposed adjustment to reflect the expected increases in wages under the IPPS low wage index hospital policy. We are proposing to establish the adjustments for the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

12. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs and other entities.

13. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2021 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

14. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2020 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2020 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at: *http://www.medpac.gov*.

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their health information. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance

interoperability across settings of care, including post-acute care.

To further interoperability in across all care settings, CMS continues to explore opportunities to advance electronic exchange of patient information across payers, providers and with patients, including developing systems that use nationally recognized health IT standards such as Logical Observation Identifier Names and Codes (LOINC), Systemized Nomenclature of Medicine-Clinical Terms (SNOMED), and Fast Healthcare Interoperability Recourses (FHIR). In addition, CMS and ONC are collaborating with industry stakeholders via the Post-Acute Care Interoperability Workgroup (PACIO) (to develop FHIR-based standards for post-acute care (PAC) assessment content, which could support the exchange and reuse of patient *http://pacioproject.org/*) assessment data derived from the Minimum Data Set (MDS), Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), Long Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LTCH CARE data set), Outcome Assessment Information Set (OASIS) assessment tools, and other sources. The Data Element Library (DEL) (*https://del.cms.gov/DELWeb/pubHome*) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision-making. Standards in the DEL (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2020 ISA is available at *https://www.healthit.gov/isa*.

In the September 30, 2019 **Federal Register**, we published a final rule titled, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51836) (''Discharge Planning final rule''), that revises the discharge planning requirements that hospitals (including psychiatric hospitals, long-term care hospitals, and inpatient rehabilitation facilities), critical access hospitals (CAHs), and home health agencies, must meet to participate in Medicare and Medicaid programs. It also revises one provision regarding patient rights in hospitals. The rule supports our interoperability efforts by promoting the exchange of patient information between health care settings, and by ensuring that a patient's necessary medical information is transferred with the patient after discharge from a hospital, CAH, or post-acute care services provider. For more information on the discharge planning requirements, please visit the final rule at: *https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals*.

We invite providers to learn more about these important developments and how they are likely to affect LTCHs and encourage the electronic exchange of health data across care settings and with patients.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. (Beginning in FY 2008, CMS adopted the Medicare-Severity DRGs (MS–DRGs) to better recognize severity of illness and resource use based on case complexity.) Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs. Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2020 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, 83 FR 41158 through 41258, and 84 FR 42058 through 42165, respectively).

C. FY 2021 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA).

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses. In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We

provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FY 2018, FY 2019, and FY 2020 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157) and in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019 and FY 2020, respectively. We indicated that the FY 2018, FY 2019, and FY 2020 adjustments were permanent adjustments to payment rates. We also stated that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2021 through 2023 in future rulemaking.

3. Adjustment for FY 2021

Consistent with the requirements of section 414 of the MACRA, we proposed to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2021. We indicated that this would constitute a permanent adjustment to payment rates. We stated in the proposed rule that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2022 through 2023 in future rulemaking.

Comment: Commenters stated that in order to comply with ATRA requirements, CMS anticipated that a cumulative −3.2 percentage point adjustment to the standardized amount would achieve the mandated $11 billion recoupment. A commenter stated that by retaining the −0.7 percentage point adjustment made in FY 2017, CMS has miscalculated the directives issued by Congress, and has contravened Congress' clear instructions and intent. The commenter contends that when Section 15005 of the 21st Century Cures Act (Pub. L. 114–255) altered the positive adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points, Congress recognized that this difference would not be restored. According to the commenter, Congress thus assumed that the 0.7 percentage point adjustment would be returned as part of the restoration process; otherwise, it would have updated the ''baseline'' to reflect CMS' revised total negative adjustment of 3.9%. A commenter asserted that the additional −0.7 percentage point adjustment made in FY 2017 has been improperly continued in FY 2018, FY 2019, and FY 2020, and failure to restore the additional 0.7 percentage point adjustment will cause hospitals to experience a significant cut in their reimbursement for FY 2021 (in addition to the losses already incurred for FYs 2018, 2019, and 2020). Other commenters urged CMS to use its exceptions and adjustments authority under section 1886(d)(5)(I) by FY 2024, to restore an additional 0.7 percentage point payment adjustment to restore payment equity to hospitals and comply with what they asserted was Congressional intent. Another commenter suggested CMS implement an approximate positive adjustment of 1.0 percentage point by FY 2024 to fully and permanently restore the entire −3.9 percentage point recoupment adjustment to IPPS rates.

Response: As we discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32471), and in response to similar comments in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), we believe section 414 of the MACRA and section 15005 of the 21st Century Cures Act set forth the levels of positive adjustments for FYs 2018 through 2023. We are not convinced that the adjustments prescribed by MACRA were predicated on a specific adjustment level estimated or implemented by CMS in previous rulemaking. While we had anticipated making a positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA, section 414 of the MACRA required that we implement a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023, and not the single positive adjustment we intended to make in FY 2018. As discussed in the FY 2017 IPPS/LTCH PPS final rule, by phasing in a total positive adjustment of only 3.0 percentage points, section 414 of the

MACRA would not fully restore even the 3.2 percentage point adjustment originally estimated by CMS in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515). Moreover, as discussed in the FY 2018 IPPS/LTCH PPS final rule, Public Law 114–255, which further reduced the positive adjustment required for FY 2018 from 0.5 percentage point to 0.4588 percentage point, was enacted on December 13, 2016, after CMS had proposed and finalized the final negative −1.5 percentage point adjustment required under section 631 of the ATRA. We see no evidence that Congress enacted these adjustments with the intent that CMS would make an additional +0.7 percentage point adjustment in FY 2018 to compensate for the higher than expected final ATRA adjustment made in FY 2017, nor are we persuaded that it would be appropriate to use the Secretary's exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to adjust payments in FY 2021 to restore any additional amount of the original 3.9 percentage point reduction, given Congress' prescriptive adjustment levels under section 414 of the MACRA and section 15005 of the 21st Century Cures Act. We intend to address adjustments for FY 2022 and later years in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to implement a 0.5 percentage point adjustment to the standardized amount for FY 2021.

D. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2021 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for FY 2021 MS–DRG Updates

Given the need for more time to carefully evaluate requests and propose updates, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), we changed the deadline to request updates to the MS–DRGs to November 1 of each year, which provided an additional 5 weeks for the data analysis and review process. Interested parties had to submit any comments and suggestions for FY 2021 by November 1, 2019, and the comments that were submitted in a timely manner for FY 2021 are discussed in this section of the preamble of this final rule. As we discuss in the sections that follow, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking.

We stated in the proposed rule that with the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and in order to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any updates. Therefore, we stated that we are changing the deadline to request changes to the MS–DRGs to October 20th of each year to allow for additional time for the review and consideration of any updates. We stated that interested parties should submit any comments and suggestions for FY 2022 by October 20, 2020 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*.

Comment: A commenter expressed concern that changing the deadline to submit requested changes to the MS–DRGs from November 1st to October 20th will shorten the amount of time that hospitals have to review the final rule each year and determine how changes may impact MS–DRG recommendations for the following year. The commenter opposed the change in date stating hospitals should be given more time to evaluate impacts of the MS–DRG changes. We also received comments urging CMS to consider the impact of the COVID–19 pandemic on the FY 2020 MedPAR data in evaluating potential MS–DRG changes for FY 2022. Commenters noted that the volume for MS–DRGs unrelated to COVID–19 hospitalizations may not be typical as a result of the postponement or cancellation of elective surgeries.

Response: We believe that a change in the deadline from November 1st to October 20th will continue to provide hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations. As noted later in this section, in response to prior public comments, we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 38 containing the proposed GROUPER logic for FY 2021 in connection with the proposed rule, allowing providers to build case examples reflecting the proposed MS–DRG changes. Therefore, we believe providers have sufficient time to assess potential impacts. However, because of the unique circumstance for this final rule for which we are waiving the delayed effective date (as discussed in section I.A.2 of this preamble), we are maintaining the deadline of November 1, 2020 for FY 2022 MS–DRG classification change requests, and expect to reconsider a change in the deadline beginning with comments and suggestions submitted for FY 2023. In response to the public comments received expressing concerns about evaluating potential MS–DRG changes for FY 2022 using the FY 2020 MedPAR claims data, which may reflect various impacts as a result of the COVID–19 pandemic, we will consider these concerns in developing FY 2022 proposals. Accordingly, interested parties should submit any comments and suggestions for FY 2022 by November 1, 2020 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*.

Based on public comments received in response to the FY 2020 IPPS/LTCH PPS proposed rule, we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 38, in connection with the FY 2021 IPPS/LTCH PPS proposed rule so that the public could better analyze and understand the impact of the proposals included in the proposed rule. We noted that this test software reflects the proposed GROUPER logic for FY 2021. Therefore, it includes the new diagnosis

and procedure codes that are effective for FY 2021 as reflected in Table 6A.—New Diagnosis Codes—FY 2021 and Table 6B.—New Procedure Codes—FY 2021 that were associated with the proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2021 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2021 that was associated with the proposed rule. We also noted that there were not any procedure codes that had been designated as invalid for FY 2021 at the time of the development of the proposed rule. Those tables were not published in the Addendum to the proposed rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to the proposed rule. Because the diagnosis codes no longer valid for FY 2021 are not reflected in the test software, we made available a supplemental file in Table 6P.1a that includes the mapped Version 38 FY 2021 ICD–10–CM codes and the deleted Version 37 FY 2020 ICD–10–CM codes that should be used for testing purposes with users' available claims data. Therefore, users had access to the test software allowing them to build case examples that reflect the proposals that were included in the proposed rule. In addition, users were able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 38.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 38, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 38, and the supplemental mapping file in Table 6P.1a of FY 2020 and FY 2021 ICD–10–CM diagnosis codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software*.

Following are the changes that we proposed to the MS–DRGs for FY 2021. We invited public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. For the FY 2021 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2019 update of the FY 2019 MedPAR file, which contains hospital bills received through September 30, 2019, for discharges occurring through September 30, 2019. In our discussion of the proposed MS–DRG reclassification changes, we referred to these claims data as the ''September 2019 update of the FY 2019 MedPAR file.''

In this FY 2021 IPPS/LTCH PPS final rule, we summarize the public comments we received on our proposals, present our responses, and state our final policies. For this FY 2021 final rule, we generally did not perform any further MS–DRG analysis of claims data. Therefore, our MS–DRG analysis is based on ICD–10 claims data from the September 2019 update of the FY 2019 MedPAR file, which contains hospital bills received through September 30, 2019, for discharges occurring through September 30, 2019, except as otherwise noted.

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent;
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup;
- At least 500 cases are in the CC or MCC subgroup;
- There is at least a 20-percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to expand the previously listed criteria to also include the NonCC subgroup. We explained that we believe that applying these criteria to the NonCC subgroup would better reflect resource stratification and also promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs.

Specifically, in our analysis of the MS–DRG classification requests for FY 2021 that we received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC and NonCC subgroups, as described in the following table. We provided the following table to better illustrate all five criteria and how they are applied for each CC subgroup, including their application to the NonCC subgroup beginning with the FY 2021 proposed rule. We also stated we had revised the order in which the criteria are presented for illustrative purposes.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for the FY 2021 IPPS/LTCH PPS proposed rule and this final rule, our MS–DRG analysis is based on ICD–10 claims data from the September 2019 update of the FY 2019 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we analyze the most recent 2 years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria are satisfied for a three way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two way split. If the criteria for both of the two way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three way split fails on any one of the five criteria and all five criteria for both two way splits (1_23 and 12_3) are met, we would apply the two way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two way splits, however we do not also evaluate the criteria for a three way split.

Comment: A commenter acknowledged CMS's proposal to expand the previously listed criteria to create subgroups to also include the NonCC subgroup. This commenter expressed concern that the proposed principles are limited and restrictive and more applicable to MCCs than CCs.

Response: It is not clear to us from the limited discussion in the comment why the commenter believes the principles are limited and restrictive and more applicable to MCCs than CCs, as the commenter did not provide further information or examples of this, nor suggest alternative approaches. We note that the criteria to create subgroups within the MS–DRGs as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32472 through 32473) are separate from the guiding principles we discussed in the context of the comprehensive CC/MCC analysis of diagnosis codes when reported as a secondary diagnosis (85 FR 32550). However, the commenter did not provide any further information, alternative suggestions or recommendations with respect to either analysis.

Comment: A commenter noted that in CMS's analysis of the MS–DRG classification requests for FY 2021, the proposed expanded criteria were applied to each of the MCC, CC and NonCC subgroups and it questioned the appropriateness of applying the proposed subgroup criteria to include the NonCC subgroup for FY 2021 prior to it being finalized. This commenter also requested that CMS clarify how it will apply the proposed expansion of the subgroup criteria going forward. The commenter stated that if CMS were to apply the NonCC subgroup criteria retroactively in future rulemaking there are concerns with implications on the MS–DRG groupings and relative weights. The commenter conducted its own preliminary analysis using the FY 2018 MedPAR data and noted that some MS–DRGs with three subgroups would have two subgroups under the new framework and it was not clear how this may impact the relative weights of those MS–DRGs.

Response: In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to expand the existing criteria to create subgroups within a base MS–DRG to include the NonCC subgroup (85 FR 32472 through 32473). We noted that in our analysis of the MS–DRG classification requests for FY 2021, we applied the proposed criteria to each of the MCC, CC and NonCC subgroups. In response to the commenter's concern about the appropriateness of applying

the proposed subgroup criteria for MS–DRG classification requests in FY 2021 prior to it being finalized, we note that we proposed and requested comments on the expansion of these criteria to the NonCC subgroup as part of this rulemaking and before finalization of this approach for FY 2021 MS–DRG changes. We also note that in the absence of applying the proposed criteria to include the NonCC subgroup, the MS–DRG related proposals for FY 2021 involving such requests to create subgroups would have similar results. However, to better illustrate for the reader the criteria that were established in FY 2008 (72 FR 47169) to determine if the creation of a new CC or MCC subgroup within a base MS–DRG is warranted, we have provided this table.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

As shown in the table, under column number two (Three-Way Split), the first criterion requires ''500+ cases for MCC group; and 500+ cases for CC group'' and the second criterion requires ''5%+ cases for MCC group; and 5%+ cases for CC group''. We note that there is no volume or percentage of cases requirement for the NonCC group under the first and second criterion for this type of severity level split under the existing criteria. We further note that the proposed expansion of the criteria to include the NonCC subgroup, as discussed in the proposed rule, is only applicable for a three-way split because as previously illustrated in the table, the criteria for the NonCC subgroup already exists in each of the options for a two-way split.

As stated previously, in the absence of applying the proposed criteria to include the NonCC subgroup, the MS–DRG related proposals for FY 2021 involving such requests to create subgroups would have similar results. For example, in response to the request under the Pre-MDC category to split MS–DRG 014 (Allogeneic Bone Marrow Transplant) into two severity levels, based on the presence of a MCC, we discussed our application of the criteria to create subgroups for each of the two-way severity level splits. We noted that the criterion that there be at least 500 cases for each subgroup (with MCC and without MCC) failed due to low volume, for both years analyzed. The analysis did not specifically rely on application of the proposed expansion of the criteria for the NonCC subgroup since the request was not for a three-way severity split and we noted there was already an insufficient volume of cases (less than 500) in the CC subgroup (CC+NonCC group). Another example under the Pre-MDC category is for the proposed new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), for which we received public comments regarding CC subgroups and is discussed in further detail in section II.E.2.b. of the preamble of this final rule.

We take this opportunity to clarify that there are no plans to apply the proposed expansion of the criteria to the NonCC subgroup retroactively in future rulemaking. The commenter is correct that application of the proposed NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels under the proposed new framework. Any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in the Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

After consideration of the public comments we received, we are finalizing our proposal to expand the previously listed criteria to also include the NonCC subgroup.

We are making the FY 2021 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 38, the ICD–10 MS–DRG Definitions Manual files Version 38 and the Definitions of Medicare Code Edits Manual Version 38 available to the public on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

2. Pre-MDC

a. Bone Marrow Transplants

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32473 through 32475), we received two separate requests that involve the MS–

DRGs where bone marrow transplant procedures are assigned. The first request was to redesignate MS–DRG 014 (Allogeneic Bone Marrow Transplant), MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy), and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) from surgical MS–DRGs to medical MS–DRGs. According to the requestor, bone marrow transplant procedures involve a transfusion of donor cells and do not involve a surgical procedure or require the resources of an operating room (O.R.). The second request involving bone marrow transplant procedures was to split MS–DRG 014 (Allogeneic Bone Marrow Transplant) into two severity levels, based on the presence of a MCC. In this section of this rule, we discuss each request in more detail.

With regard to the first request, the requestor noted that the logic for MS–DRG 014 consists of ICD–10–PCS procedure codes describing allogeneic bone marrow transplants that are designated as non-operating room (non-O.R.) procedures. The requestor also noted that the logic for MS–DRGs 016 and 017 includes ICD–10–PCS procedure codes describing autologous bone marrow transplants where certain procedure codes are designated as O.R. and other procedure codes are designated as non-O.R. procedures. The requestor stated that redesignating the bone marrow transplant MS–DRGs from surgical to medical would clinically align with the resources utilized in the performance of these procedures.

The requestor is correct that bone marrow transplant procedures are currently assigned to MS–DRGs 014, 016, and 017 which are classified as surgical MS–DRGs under the Pre-MDC category for the ICD–10 MS–DRGs. The requestor is also correct that the logic for MS–DRG 014 consists of ICD–10–PCS procedure codes describing allogeneic bone marrow transplants that are designated as non-operating room (non-O.R.) procedures and that the logic for MS–DRGs 016 and 017 includes ICD–10–PCS procedure codes describing autologous bone marrow transplants where certain procedure codes are designated as O.R. procedures and other procedure codes are designated as non-O.R. procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 37 which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 014, 016, and 017.

As noted in the proposed rule, we consulted with our clinical advisors and they agreed that bone marrow transplant procedures are similar to a blood transfusion procedure, do not utilize the resources of an operating room, and are not surgical procedures. Our clinical advisors concurred that bone marrow transplants are medical procedures and it is more accurate to designate the MS–DRGs to which these procedures are assigned as medical MS–DRGs versus surgical MS–DRGs. Therefore, we proposed to redesignate MS–DRGs 014, 016, and 017 as medical MS–DRGs effective October 1, 2020 for FY 2021.

As noted previously, the logic for MS–DRGs 016 and 017 includes ICD–10–PCS procedure codes describing autologous bone marrow transplants and related procedures where certain procedure codes are designated as O.R. and other procedure codes are designated as non-O.R. procedures. We stated in the proposed rule that during our review of the bone marrow transplant procedures assigned to these MS–DRGs, we identified the following 8 procedure codes that are currently designated as O.R procedures.

ICD-10-PCS Code	Code Description
30230AZ	Transfusion of embryonic stem cells into peripheral vein, open approach
30230G0	Transfusion of autologous bone marrow into peripheral vein, open approach
30230X0	Transfusion of autologous cord blood stem cells into peripheral vein, open approach
30230Y0	Transfusion of autologous hematopoietic stem cells into peripheral vein, open approach
30240AZ	Transfusion of embryonic stem cells into central vein, open approach
30240G0	Transfusion of autologous bone marrow into central vein, open approach
30240X0	Transfusion of autologous cord blood stem cells into central vein, open approach
30240Y0	Transfusion of autologous hematopoietic stem cells into central vein, open approach

In connection with our proposal to designate the MS–DRGs to which these procedures are assigned as medical, as well as for clinical consistency with the other procedure codes describing bone marrow transplant procedures, we proposed to redesignate the listed ICD–10–PCS procedure codes from O.R. to non-O.R. procedures, affecting their current MS–DRG assignment for MS–DRGs 016 and 017, effective October 1, 2020 for FY 2021.

As discussed in the proposed rule and noted earlier in this section, we also received a request to split MS–DRG 014 (Allogeneic Bone Marrow Transplant) into two severity levels, based on the presence of a MCC. For FY 2020, the requestor had requested that MS–DRG 014 be split into two new MS–DRGs according to donor source. For the reasons discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19176 through 19180) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42067 through 42072), we did not propose to split MS–DRG 014 into two new MS–DRGs according to donor source. However, according to the requestor, a single (base) MS–DRG for allogeneic bone marrow and stem cell transplants continues to not be as clinically or resource homogeneous as it could be. The requestor conducted its own analysis and stated the results revealed it was appropriate to split MS–DRG 014 based on the presence of a MCC.

We noted in the proposed rule that we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRG 014. There were 962 cases found in MS–DRG 014 with an average length of stay of 26.7 days and average costs of $89,586.

As stated in the proposed rule, consistent with our established process, we conducted an analysis of MS–DRG 014 to determine if the criteria to create subgroups were met. The process for conducting this type of analysis includes examining 2 years of MedPAR claims data to compare the data results

from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 014 using the September 2018 update of the FY 2018 MedPAR file and the September 2019 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2021. Our findings are shown in the table.

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases Non CC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs Non CC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	962	779	141	42	$89,586	$94,840	$69,287	$60,277	$90,924	$67,219
2018	982	807	140	35	$90,759	$95,075	$69,785	$75,157	$91,336	$70,859

We applied the criteria to create subgroups for each of the two-way severity level splits. As discussed in section II.D.1.b., in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to expand the previously listed criteria to also include the NonCC group. The criterion that there be at least 500 cases for each subgroup failed due to low volume, as shown in the table for both years. Specifically, for the ''with MCC'' and ''without MCC'' (CC+NonCC) split, there were only 183 (141+42) cases in the ''without MCC'' subgroup based on the data in the FY 2019 MedPAR file and only 175 (140+35) cases in the ''without MCC'' subgroup based on the data in the FY 2018 MedPAR file. For the ''with CC/MCC'' and ''without CC/MCC'' (NonCC) split, there were only 42 cases in the NonCC subgroup based on the data in the FY 2019 MedPAR file and only 35 cases in the NonCC subgroup based on the data in the FY 2018 MedPAR file. The claims data do not support a two-way severity level split for MS–DRG 014, therefore, we proposed to maintain the current structure of MS–DRG 014 for FY 2021.

Comment: Commenters supported the proposal to redesignate MS–DRGs 014, 016, and 017 as medical MS–DRGs and stated they agreed that bone marrow transplant procedures are medical procedures that do not utilize the resources of an operating room. However, the commenters also noted that bone marrow transplants remain resource intensive procedures and the patients are medically complex, often requiring additional monitoring and increased lengths of stay. Commenters also agreed that the ICD–10–PCS procedure codes describing bone marrow transplants should have the same designation and supported the proposal to redesignate the eight ICD–10–PCS procedure codes listed in the previous table from O.R. to non-O.R. procedures, affecting their current MS–DRG assignment for MS–DRGs 016 and 017. However, a single commenter disagreed with the proposal to redesignate the eight ICD–10–PCS procedure codes listed in the previous table from O.R. to non-O.R. procedures stating that the proposal did not provide any detail as to how the codes would be reassigned and recommended not finalizing the proposal until more information was provided in future rulemaking. Another commenter noted that the bone marrow transplant procedure codes represent an example of why the current process of determining whether a procedure qualifies for designation as an O.R. procedure may be outdated. This commenter acknowledged CMS' discussion from section II.D.11. in the proposed rule that stated while procedures have typically been evaluated on the basis of whether they would be performed in an operating room, there may be other factors to consider with regard to resource consumption (85 FR 32542 through 32549). Another commenter reported that in review of the eight procedure codes CMS proposed to redesignate from O.R. to non-O.R., they queried the FY 2019 MedPAR claims data and discovered a limited number of claims reflecting these procedure codes. This commenter consulted with its clinical advisors to determine if a bone marrow transplant with an ''open approach'' (as described by the procedure codes and the ICD–10–PCS classification), would generally occur. According to the clinical advisors, it is illogical to maintain these procedure codes describing an open approach for allogeneic and autologous bone marrow transplant procedures. The commenter recommended that CMS remove the procedure codes identified with an open approach from the classification.

Commenters also supported retaining the structure of MS–DRG 014 and not creating a two-way severity level split based on the data and information provided. A commenter stated they understood and did not dispute CMS' logic based on the criteria to create subgroups, however, they suggested that when proposals from the comprehensive CC/MCC analysis are finalized that this MS–DRG be reevaluated given the variation in the ''with CC/MCC'' and ''without CC/MCC'' subgroups ($90,924 versus $60,277, respectively) displayed in the CMS data analysis. In addition, this commenter noted that the FY 2020 proposals related to the CC/MCC analysis involved redesignating the neoplasm codes from CC to NonCC and stated their belief that facilities addressing the costly and unavoidable consequences of allogeneic bone marrow transplants should be compensated for providing the care.

Response: We appreciate the commenters' support for our proposals related to MS–DRGs 014, 016 and 017 for bone marrow transplant procedures. We agree with the commenters that bone marrow transplants are resource intensive procedures and the patients are medically complex, often requiring additional monitoring and increased lengths of stay. In response to the commenter who disagreed with the proposal to redesignate the eight ICD–10–PCS procedure codes listed in the previous table from O.R. to non-O.R. procedures because the proposal did not provide any detail as to how the codes would be reassigned and recommended not finalizing the proposal until more information was provided in future rulemaking, we note that the proposed rule specifically stated ''we are proposing to redesignate the listed ICD–10–PCS procedure codes from O.R. to non-O.R. procedures, affecting their current MS–DRG assignment for MS–DRGs 016 and 017, effective October 1, 2020 for FY 2021''. As we also discussed in section II.D.11.a. of the proposed rule, each procedure that is designated as a non-O.R. procedure is

further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We noted that the non-O.R. designations that do affect the MS–DRG are referred to as ''non-O.R. affecting the MS–DRG.'' Accordingly, redesignating these eight procedure codes as non-O.R. procedures affecting their MS–DRG assignment means that they are non-O.R. and will continue to be assigned to MS–DRGs 016 and 017 for FY 2021.

In response to the commenter who recommended that CMS remove the procedure codes describing an allogeneic or autologous bone marrow transplant with an open approach from the classification, we thank the commenter for their suggestion and note that proposed changes to these procedure codes can be considered at an ICD–10 Coordination and Maintenance Committee meeting. As discussed in section II.E.16. of the preamble of this final rule, we encourage commenters to submit proposals for procedure coding changes via Email to: *ICDProcedure CodeRequest@cms.hhs.gov*.

With regard to the commenter who suggested that MS–DRG 014 be reevaluated when proposals from the comprehensive CC/MCC analysis are finalized due to the variation in the ''with CC/MCC'' and ''without CC/MCC'' subgroups as displayed in the CMS data analysis, we note that we will evaluate and analyze data for all the MS–DRGs consistent with our annual process.

After consideration of the public comments that we received, we are finalizing our proposal to redesignate MS–DRGs 014, 016, and 017 from surgical to medical MS–DRGs under the Pre-MDC category and finalizing our proposal to redesignate the eight ICD–10–PCS procedure codes listed in the previous table from O.R. to non-O.R. procedures, affecting their current MS–DRG assignment for MS–DRGs 016 and 017 for FY 2021. We are also finalizing our proposal to maintain the current structure of MS–DRG 014 for FY 2021.

b. Chimeric Antigen Receptor (CAR) T-Cell Therapies

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32475 through 32476), we discussed several requests we received to create a new MS–DRG for procedures involving CAR T-cell therapies. The requestors stated that creation of a new MS–DRG would improve payment for CAR T-cell therapies in the inpatient setting. Some requestors noted that cases involving CAR T-cell therapies will no longer be eligible for new technology add-on payments in FY 2021 and that this would significantly reduce the overall payment for cases involving CAR T-cell therapies. Some requestors also noted that in the absence of the creation of a new MS–DRG for procedures involving CAR T-cell therapies, outlier payments for these cases would increase significantly, which would increase the share of total outlier payments that are attributable to CAR T-cell therapies.

The requestors stated that the new MS–DRG for CAR T-cell therapies should include cases that report ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3).

Given the high cost of the CAR T-cell product, some requestors provided recommendations related to the differential treatment of cases where the CAR T-cell product was provided without cost as part of a clinical trial to ensure that the payment amount for the newly created MS–DRG for CAR T-cell therapy cases would appropriately reflect the average cost hospitals incur for providing CAR T-cell therapy outside of a clinical trial. For example, some requestors suggested that CMS make minor adjustments to its usual ratesetting methodology to exclude clinical trial claims from the calculation of the relative weight for any MS–DRG for CAR T-cell therapies. One requestor noted that these adjustments are consistent with CMS' general authority under sections 1886(d)(4)(B) and (C) of the Act. Some requestors also suggested that CMS apply an offset to the MS–DRG payment in cases where the provider does not incur the cost of the CAR T-cell therapy.

Currently, procedures involving CAR T-cell therapies are identified with ICD–10–PCS procedure codes XW033C3 and XW043C3, which became effective October 1, 2017. In the FY 2019 IPPS/LTCH PPS final rule, we finalized our proposal to assign cases reporting these ICD–10–PCS procedure codes to Pre-MDC MS–DRG 016 for FY 2019 and to revise the title of this MS–DRG to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy''. We refer readers to section II.F.2.d. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a complete discussion of these final policies (83 FR 41172 through 41174).

As noted, the current procedure codes for CAR T-cell therapies both became effective October 1, 2017. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174), we indicated that we believed we should collect more comprehensive clinical and cost data before considering assignment of a new MS–DRG to these therapies. We stated in the FY 2020 IPPS/LTCH PPS proposed rule that, while the September 2018 update of the FY 2018 MedPAR data file does contain some claims that include those procedure codes that identify CAR T-cell therapies, the number of cases is limited, and the submitted costs vary widely due to differences in provider billing and charging practices for this therapy. Therefore, while those claims could potentially be used to create relative weights for a new MS–DRG, we stated that we did not have the comprehensive clinical and cost data that we generally believe are needed to do so. Furthermore, we stated in the FY 2020 IPPS/LTCH PPS proposed rule that given the relative newness of CAR T-cell therapy and our proposal to continue new technology add-on payments for FY 2020 for the two CAR T-cell therapies that currently have FDA approval (KYMRIAH™ and YESCARTA™), at the time we believed it was premature to consider creation of a new MS–DRG specifically for cases involving CAR T-cell therapy for FY 2020. We stated that in future years we would have additional data that could be used to evaluate the potential creation of a new MS–DRG specifically for cases involving CAR T-cell therapies.

We stated in the FY 2021 IPPS/LTCH PPS proposed rule that we now have more data upon which to evaluate a new MS–DRG specifically for cases involving CAR T-cell therapies. We stated that we agree with the requestors it is appropriate to consider the development of a new MS–DRG using the data that is now available. We examined the claims data from the September 2019 update of the FY 2019 MedPAR data file for cases that reported ICD–10–PCS procedure codes XW033C3 or XW043C3. For purposes of this analysis, we identified clinical trial cases as claims with ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) which is reported only for clinical trial cases, or with standardized drug charges of less than $373,000, which is the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell medicines approved to treat relapsed/refractory diffuse large B-cell lymphoma as of the time of the development of the proposed rule and this final rule. We stated that we

distinguished between clinical trial and non-clinical trial cases in this analysis because we agree with the requestors who indicated that given the high cost of the CAR T-cell product, it is appropriate to distinguish cases where the CAR T-cell product was provided without cost as part of a clinical trial so that the analysis appropriately reflects the resources required to provide CAR T-cell therapy outside of a clinical trial. We also noted that we included cases that would have been identified as statistical outliers under our usual process when examined as part of MS–DRG 016 due to the extreme cost differences between the CAR T-cell therapy claims and other claims in MS–DRG 016, but would not be identified as statistical outliers when examining CAR T-cell therapy claims only. Our findings are shown in the table.

MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
016	All Cases		2,212	18.2	$55,001
	ICD-10-PCS codes XW033C3 or XW043C3	All cases	262	16.3	$127,408
		Non-clinical trial cases	94	17.2	$274,952
		Clinical trial cases	168	15.8	$44,853

*We note that we included 18 cases that were flagged as statistical outliers in our trim methodology due to the mix of CAR T- cell therapy and non-CAR T - cell therapy cases in the current MS-DRG.

*We note that we included 18 cases that were flagged as statistical outliers in our trim methodology due to the mix of CAR T- cell therapy and non-CAR T—cell therapy cases in the current MS–DRG.

As shown in the table, we found 2,212 cases in MS–DRG 016, with an average length of stay of 18.2 days and average costs of $55,001. Of these 2,212 cases, 262 cases reported ICD–10–PCS procedure codes XW033C3 or XW043C3; these cases had an average length of stay of 16.3 days and average costs of $127,408. Of these 262 cases, 94 were identified as non-clinical trial cases; these cases had an average length of stay of 17.2 days and average costs of $274,952. The remaining 168 cases were identified as clinical trial cases; these cases had an average length of stay of 15.8 days and average costs of $44,853.

The data indicate that the average costs for the non-clinical trial cases that reported ICD–10–PCS procedure codes XW033C3 or XW043C3 are almost five times higher than the average costs for all cases in MS–DRG 016. We stated that our clinical advisors also believe that the cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 can be clinically differentiated from other cases that group to MS–DRG 016, which includes procedures involving autologous bone marrow transplants, once the CAR T-cell therapy itself is taken into account in the comparison.

As described earlier in this section, in deciding whether to propose to make modifications to the MS–DRGs for particular circumstances brought to our attention, we consider a variety of factors pertaining to resource consumption and clinical characteristics. We stated in the proposed rule that while we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, our clinical advisors believe that the vast discrepancy in resource consumption as reflected in the claims data analysis and the clinical differences warrant the creation of a new MS–DRG. We therefore proposed to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy).

We stated in the proposed rule that if additional procedure codes describing CART- cell therapies are approved and finalized, we would use our established process to assign these procedure codes to the most appropriate MS–DRG. Because these cases would no longer group to MS–DRG 016, we proposed to revise the title for MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy'' to ''Autologous Bone Marrow Transplant with CC/MCC''.

Comments: The vast majority of commenters supported CMS' proposal to create new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), stating that it will better reflect the resource use involved in providing the CAR T-cell therapy. Commenters acknowledged that CMS had considered many factors previously raised by stakeholders in developing this new MS–DRG. A small number of commenters did not support the creation of a new MS–DRG and recommended that CMS maintain the new technology add-on payment for CAR T-cell therapies, delay creating a new MS–DRG, and consider public-private partnerships for data collection.

Response: We appreciate commenters' support. With respect to commenters that requested that we instead maintain the new technology add-on payments, we refer the reader to the section of this rule where we address these comments. We believe that the data we currently have available is sufficient to establish a relative weight at this time, and therefore do not believe it is appropriate to delay the creation of a new MS–DRG. We also note that the weights are recalibrated yearly to reflect additional data as it becomes available. We note that the commenter did not provide additional detail regarding potential public/private partnerships with respect to data collection.

Comments: Some commenters requested that CMS clarify that all CAR T-cell therapy products, or more

broadly, all T-cell immunotherapy products, would be assigned to MS–DRG 018 regardless of cost. One commenter expressed concern that MS–DRG 018 is specific to one mechanistic approach to cellular therapy and has not provided for the array of cellular therapies in development.

Response: As we stated in the proposed rule, if additional procedure codes describing CART-cell therapies are approved and finalized, we would use our established process to assign these procedure codes to the most appropriate MS–DRG. As described in the FY 2020 final rule (84 FR 42061), assigning new procedure codes involves review of the predecessor procedure code's MS–DRG assignment. However, this process does not automatically result in the new procedure code being assigned (or proposed for assignment) to the same MS–DRG as the predecessor code. There are several factors to consider during this process that our clinical advisors take into account. For example, in the absence of volume, length of stay, and cost data, they may consider the specific service, procedure, or treatment being described by the new procedure code, the indications, treatment difficulty, and the resources utilized. Similarly, should additional cellular therapies become available, we would use our established process to determine whether there is a need to reconsider the MS–DRG assignment that would otherwise result from the principal diagnosis and other factors that go into MS–DRG assignment.

Comments: Some commenters requested that CMS consider subdividing MS–DRG 018 into separate MS–DRGs for MCCs, CCs, and non-CCs in order to account for the higher costs involved in caring for patients who develop Cytokine Release Syndrome (CRS). Some commenters requested that payments consider factors such as patients' burden of illness, comorbid conditions and complications associated with receiving CAR T-cell therapy treatment and consider complications and/or comorbidity or major complications or comorbidity codes when evaluating reimbursement for CAR T-cell therapies as more clinical data become available.

Response: As discussed in the proposed rule (85 FR 32472 through 32473), one of the criteria for the creation of a new complication or comorbidity or major complication or comorbidity subgroup within a base MS–DRG is at least 500 cases are in the CC or MCC subgroup which, as discussed previously in this section, we are finalizing to also expand to the NonCC subgroup beginning with FY 2021. As noted previously, we identified 262 total cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 in MS–DRG 016 based on the data from the September 2019 update of the FY MedPAR file. We may consider the creation of subgroups within MS–DRG 018 in future rulemaking once additional data is available.

Comments: Some commenters requested that CMS create two new cost centers; one for cell therapy products, tied to revenue code 891, and one for gene therapy products, tied to revenue code 892. A commenter suggested that the use of a dedicated cost center would improve the accuracy of cost estimates since it would allow the creation of a separate CCR for CAR T-cell therapy products, and would not rely on hospitals setting their charges for CAR T-cell therapy products at very high levels. Commenters acknowledged that this would also require that CMS modify the cost report to break out these revenue centers. Other commenters requested that CMS issue a Medicare Learning Network (MLN) article instructing hospitals regarding adjustment of charges for CAR T-cell therapy products, while another commenter suggested that CMS could create a standardized charging protocol for CAR T-cell therapy products.

Response: We appreciate the commenters' request regarding the creation of new cost centers for revenue codes 891 and 892 and may consider this request in future rulemaking. With respect to the commenters who expressed concerns about hospital charging practices, we note that there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs.

Comments: A commenter stated that the indefinite use of MS–DRG 018 under the IPPS is not sustainable. Some commenters requested that CMS consider value-based care or other alternative payment models, add-on payments, or paying on a pass-through basis, as more appropriate payment mechanisms for CAR T-cell therapies. A commenter urged CMS to continue to engage all stakeholders to develop long-term sustainable solutions that can be adapted over time and account for innovations that transform how we treat disease. Another commenter stated that the question of how to best pay for CAR T-cell therapies can best be answered by Congress, but that CMS should continue pursuing policies that enable hospitals to recoup all of their costs for providing CAR T-cell therapies. Another commenter requested that CMS create an add-on payment or otherwise modify the IPPS for pharmacy resources associated with CAR T-cell therapies.

Response: We believe that is premature to make structural changes to the IPPS at this time to pay for CAR T-cell therapies. As we gain more experience with these therapies, including the use of a separate MS–DRG for CAR T-cell therapies, we may consider these comments in future rulemaking.

We note that commenters also raised some concerns about outpatient billing instructions with respect to billing for outpatient cell collection and cell processing charges on the inpatient claim, payment issues for TEFRA hospitals, and questions regarding the MedPAR data dictionary. While we consider these comments about outpatient billing instructions and TEFRA hospitals outside of the scope of the proposals in the proposed rule, we will take these comments into consideration when developing policies and program requirements for future years. With respect to comments about the MedPAR data dictionary, we anticipate that the issues will be addressed in future MedPAR releases.

After consideration of public comments received, we are finalizing our proposal to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) and to revise the title for MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy'' to ''Autologous Bone Marrow Transplant with CC/MCC''. We refer readers to section II.E.2.b. of the preamble of this final rule for a discussion of the relative weight calculation for the new MS–DRG 018 for CAR T-cell therapy, and to section IV.I. of the preamble of this final rule for a discussion of the payment adjustment for CAR T-cell clinical trial and expanded access use immunotherapy cases.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Carotid Artery Stent Procedures

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42078), we finalized our proposal to reassign 96 ICD–10–PCS procedure codes describing dilation of carotid artery with an intraluminal device(s) from MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 034, 035, and 036 (Carotid Artery Stent Procedures with MCC, with CC, and without CC/MCC, respectively). As discussed in the FY 2021 IPPS/LTCH proposed rule (85

FR 32476), we received a request to review six ICD–10–PCS procedure codes describing dilation of a carotid artery (common, internal or external) with drug eluting intraluminal devices(s) using an open approach that were still assigned to the logic for case assignment to MS–DRGs 037, 038, and 039 that were not included in the list of codes finalized for reassignment to MS–DRGs 034, 035 and 036 in the FY 2020 IPPS/LTCH PPS final rule. The six codes are identified in the following table.

ICD-10-PCS Code	Code Description
037H04Z	Dilation of right common carotid artery with drug-eluting intraluminal device, open approach
037J04Z	Dilation of left common carotid artery with drug-eluting intraluminal device, open approach
037K04Z	Dilation of right internal carotid artery with drug-eluting intraluminal device, open approach
037L04Z	Dilation of left internal carotid artery with drug-eluting intraluminal device, open approach
037M04Z	Dilation of right external carotid artery with drug-eluting intraluminal device, open approach
037N04Z	Dilation of left external carotid artery with drug-eluting intraluminal device, open approach

The logic for case assignment to MS–DRGs 034, 035, and 036 as displayed in the ICD–10 MS–DRG Version 37 Definitions Manual, available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* is comprised of a list of logic which includes procedure codes for operating room procedures involving dilation of a carotid artery (common, internal or external) with intraluminal device(s). All of the ICD–10–PCS procedure codes in the logic list assigned to MS–DRGs 034, 035, and 036 describe dilation of a carotid artery with an intraluminal device.

In response to the request, we first examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 034, 035, and 036 which only include those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device. Our findings are reported in the following table.

MS-DRGs for Carotid Artery Stent Procedures			
MS-DRG	Number of Cases	Average Length of stay	Average Costs
034	1,259	6.9	$28,668
035	3,367	3.0	$17,114
036	4,769	1.4	$13,501

As shown in the table, we found a total of 1,259 cases in MS–DRG 034 with an average length of stay of 6.9 days and average costs of $28,668. We found a total of 3,367 cases in MS–DRG 035 with an average length of stay of 3.0 days and average costs of $17,114. We found a total of 4,769 cases in MS–DRG 036 with an average length of stay of 1.4 days and average costs of $13,501.

We then examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 037, 038, and 039 and identified cases reporting any one of the 6 procedure codes listed in the table previously to determine the volume of cases impacted and if the average length of stay and average costs are consistent with the average length of stay and average costs for MS–DRGs 034, 035 and 036. Our findings are shown in the following table.

MS-DRGs for Extracranial Procedures				
MS-DRG	**ICD-10-PCS code**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
037	All cases	3,331	7.3	$24,155
	Cases with procedure codes for dilation of a carotid artery with an intraluminal device using an open approach	6	7	$22,272
038	All cases	11,021	3.0	$12,306
	Cases with procedure codes for dilation of a carotid artery with an intraluminal device using an open approach	33	2.3	$16,777
039	All cases	20,854	1.4	$8,463
	Cases with procedure codes for dilation of a carotid artery with an intraluminal device using an open approach	26	1.2	$14,981

As shown in the table, we found a total of 3,331 cases with an average length of stay of 7.3 days and average costs of $24,155 in MS–DRG 037. There were 6 cases reporting at least one of the 6 procedure codes that describe dilation of the carotid artery with an intraluminal device using an open approach in MS–DRG 037 with an average length of stay of 7 days and average costs of $22,272. For MS–DRG 038, we found a total of 11,021 cases with an average length of stay of 3 days and average costs of $12,306. There were 33 cases reporting at least one of the 6 procedure codes that describe dilation of the carotid artery with an intraluminal device in MS–DRG 038 with an average length of stay of 2.3 days and average costs of $16,777. For MS–DRG 039, we found a total of 20,854 cases with an average length of stay of 1.4 days and average costs of $8,463. There were 26 cases reporting at least one of the 6 procedure codes that describe dilation of the carotid artery with an intraluminal device in MS–DRG 039 with an average length of stay of 1.2 days and average costs of $14,981.

The data analysis shows that for the cases in MS–DRGs 037, 038, and 039 reporting ICD–10–PCS codes 037H04Z, 037J04Z, 037K04Z, 037L04Z, 037M04Z, or 037N04Z, the average length of stay is shorter and the average costs are higher than the average length of stay and average costs (with the exception of the average costs for the 6 cases in MS–DRG 037 which are slightly less) in the FY 2019 MedPAR file for MS–DRGs 037, 038, and 039 respectively. The data analysis also shows for the cases in MS–DRGs 037, 038, and 039 reporting ICD–10–PCS codes 037H04Z, 037J04Z, 037K04Z, 037L04Z, 037M04Z, and 037N04Z the average length of stay and the average costs are in-line with the average length of stay and average costs in the FY 2019 MedPAR file for MS–DRGs 034, 035, and 036 respectively.

As noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19184) and final rule (84 FR 42077), our clinical advisors stated that MS–DRGs 034, 035 and 036 are defined to include only those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device.

Therefore, we proposed to reassign the procedure codes listed in the table from MS–DRGs 037, 038, and 039 that describe procedures that involve dilation of the carotid artery with an intraluminal device to MS–DRGs 034, 035, and 036.

In addition to our analysis of the claims data from the September 2019 MedPAR file for MS–DRGs 037, 038 and 039, we conducted an examination of all the MS–DRGs where any one of the 6 procedure codes listed previously were also reported to determine if any one of the 6 procedure codes were included in any other MS–DRG outside of MDC 01, to further assess the current MS–DRG assignments. Our findings are shown in the following table.

Other MS-DRGs Reporting Procedures Codes 037H04Z, 037J04Z, 037K04Z, 037L04Z, 037M04Z, or 037N04Z			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
023	1	13	$79,797
027	1	1	$6,838
035	1	5	$14,300
219	1	5	$65,073
233	1	18	$59,259
235	1	45	$102,530
252	1	8	$36,020

As shown in the table, we found one case reporting any one of these 6 procedure codes in each of MS–DRGs 023, 027, 035, 219, 233, 235 and 252. We noted that all of the listed MS–DRGs were assigned to MDC 01 with one exception: MS–DRG 252 (Other Vascular Procedures with MCC) in MDC05 (Diseases and Disorders of the Circulatory System). As a result, we reviewed the logic list for MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 and found 36 ICD–10–PCS codes for procedures that describe dilation of the carotid artery with an intraluminal device with an open approach that were not currently assigned in MDC 01. The 36 ICD–10–PCS codes are listed in the following table.

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Codes that Involve Dilation of a Carotid Artery with an Intraluminal Device in MDC 05 and not in MDC 01	
ICD-10-PCS Code	**Code Description**
037H05Z	Dilation of right common carotid artery with two drug-eluting intraluminal devices, open approach
037H06Z	Dilation of right common carotid artery with three drug-eluting intraluminal devices, open approach
037H07Z	Dilation of right common carotid artery with four or more drug-eluting intraluminal devices, open approach
037H0EZ	Dilation of right common carotid artery with two intraluminal devices, open approach
037H0FZ	Dilation of right common carotid artery with three intraluminal devices, open approach
037H0GZ	Dilation of right common carotid artery with four or more intraluminal devices, open approach
037J05Z	Dilation of left common carotid artery with two drug-eluting intraluminal devices, open approach
037J06Z	Dilation of left common carotid artery with three drug-eluting intraluminal devices, open approach
037J07Z	Dilation of left common carotid artery with four or more drug-eluting intraluminal devices, open approach
037J0EZ	Dilation of left common carotid artery with two intraluminal devices, open approach
037J0FZ	Dilation of left common carotid artery with three intraluminal devices, open approach
037J0GZ	Dilation of left common carotid artery with four or more intraluminal devices, open approach
037K05Z	Dilation of right internal carotid artery with two drug-eluting intraluminal devices, open approach
037K06Z	Dilation of right internal carotid artery with three drug-eluting intraluminal devices, open approach
037K07Z	Dilation of right internal carotid artery with four or more drug-eluting intraluminal devices, open approach
037K0EZ	Dilation of right internal carotid artery with two intraluminal devices, open approach
037K0FZ	Dilation of right internal carotid artery with three intraluminal devices, open approach
037K0GZ	Dilation of right internal carotid artery with four or more intraluminal devices, open approach
037L05Z	Dilation of left internal carotid artery with two drug-eluting intraluminal devices, open approach

Codes that Involve Dilation of a Carotid Artery with an Intraluminal Device in MDC 05 and not in MDC 01	
037L06Z	Dilation of left internal carotid artery with three drug-eluting intraluminal devices, open approach
037L07Z	Dilation of left internal carotid artery with four or more drug-eluting intraluminal devices, open approach
037L0EZ	Dilation of left internal carotid artery with two intraluminal devices, open approach
037L0FZ	Dilation of left internal carotid artery with three intraluminal devices, open approach
037L0GZ	Dilation of left internal carotid artery with four or more intraluminal devices, open approach
037M05Z	Dilation of right external carotid artery with two drug-eluting intraluminal devices, open approach
037M06Z	Dilation of right external carotid artery with three drug-eluting intraluminal devices, open approach
037M07Z	Dilation of right external carotid artery with four or more drug-eluting intraluminal devices, open approach
037M0EZ	Dilation of right external carotid artery with two intraluminal devices, open approach
037M0FZ	Dilation of right external carotid artery with three intraluminal devices, open approach
037M0GZ	Dilation of right external carotid artery with four or more intraluminal devices, open approach
037N05Z	Dilation of left external carotid artery with two drug-eluting intraluminal devices, open approach
037N06Z	Dilation of left external carotid artery with three drug-eluting intraluminal devices, open approach
037N07Z	Dilation of left external carotid artery with four or more drug-eluting intraluminal devices, open approach
037N0EZ	Dilation of left external carotid artery with two intraluminal devices, open approach
037N0FZ	Dilation of left external carotid artery with three intraluminal devices, open approach
037N0GZ	Dilation of left external carotid artery with four or more intraluminal devices, open approach

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We then examined the claims data to determine if there were other MS–DRGs in which one of the 36 procedure codes listed in the table were reported. We found 8 cases that grouped to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when a principal diagnosis from MDC 01 was reported with one of the procedure codes in the table that describes dilation of a carotid artery with an intraluminal device, open approach.

As noted previously, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19184) and final rule (84 FR 42077), our clinical advisors stated that MS–DRGs 034, 035, and 036 are defined to include those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device. As a result, our clinical advisors supported adding the 36 ICD–10–PCS codes identified in the table to MS–DRGs 034, 035, and 036 in MDC 01 for consistency to align with the definition of MS–DRGs 034, 035, and 036 and also to permit proper case assignment when a principal diagnosis from MDC 01 is reported with one of the procedure codes in the table that describes dilation of a carotid artery with an intraluminal device, open approach.

Therefore, for FY 2021, we also proposed to add the 36 ICD–10–PCS codes identified in the table that are currently assigned in MDC 05 to MS–

DRGs 252, 253, and 254 to the GROUPER logic for MS–DRGs 034, 035, and 036 in MDC 01.

Comment: Commenters expressed support for CMS' proposal to reassign the identified ICD–10–PCS codes describing dilation of a carotid artery with an intraluminal device from MS–DRGs 037, 038 and 039 to MS–DRGs 034, 035 and 036. Commenters also supported CMS' proposal to add the ICD–10–PCS codes describing dilation of a carotid artery with an intraluminal device currently assigned in MDC 05 to MDC 01. One commenter stated that these were positive reassignments and another stated that these reassignments will help to ensure consistency among the MS–DRG classifications for procedures involving dilation of a carotid artery with an intraluminal device.

Response: We thank the commenters for their support.

Comment: One commenter suggested that given the clinical congruence with the procedures involved with dilation of a carotid artery with an intraluminal device, procedure codes that describe vertebral and intracranial artery dilation and device placement should also be classified in MS–DRGs 034, 035 and 036, and that MS–DRG 034, 035 and 036 be renamed as Carotid, Vertebral and Intracranial Stent Procedures and requested that this recommendation be assessed and analyzed for inclusion in next year's proposed rule.

Response: We appreciate the commenter's suggestion. As stated in section II.E.1.b. of the preamble of this final rule, we encourage individuals with recommendations regarding changes to MS–DRG classification to submit these comments no later than November 1, 2020 so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

After consideration of the public comments we received, we are finalizing our proposal to reassign the 6 procedure codes discussed above from MS–DRGs 037, 038, and 039 to MS–DRGs 034, 035, and 036 because the 6 procedure codes are consistent with the other procedures describing dilation of a carotid artery with an intraluminal device that are currently assigned to

MS–DRGs 034, 035, and 036. Additionally, we are finalizing our proposal to add the 36 ICD–10–PCS codes identified in the table that are currently assigned in MDC 05 to MS–DRGs 252, 253, and 254 to the GROUPER logic for MS–DRGs 034, 035, and 036 in MDC 01.

b. Epilepsy With Neurostimulator

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32481), we received a request to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) to MS–DRG 021 (Intracranial Vascular Procedures with PDX Hemorrhage with CC) or to reassign these cases to another MS–DRG for more appropriate payment. The Responsive Neurostimulator (RNS©) System, a cranially implanted neurostimulator that is a treatment option for persons diagnosed with medically intractable epilepsy, is identified by the reporting of an ICD–10–PCS code combination capturing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain and cases are assigned to MS–DRG 023 when reported with a principal diagnosis of epilepsy.

We stated that as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019), we finalized our proposal to reassign all cases with a principal diagnosis of epilepsy and one of the following ICD–10–PCS code combinations capturing cases with a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) to MS–DRG 023 even if there is no MCC reported:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach).
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach).
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

We also finalized our change to the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemo Implant'' to ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to reflect the modifications to the MS–DRG structure.

As noted in the proposed rule, the requestor acknowledged the refinements made to MS–DRG 023 effective for FY 2018, but stated that despite the previously-stated changes, cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain continue to be underpaid. The requestor performed its own analysis and stated that it found that the average costs of cases describing the insertion of the RNS© neurostimulator were significantly higher than the average costs of all cases in their current assignment to MS–DRG 023, and as a result, cases describing the insertion of the RNS© neurostimulator are not being adequately reimbursed. The requestor suggested the following two options for MS–DRG assignment updates: (1) Reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 to MS–DRG 021 with a change in title to ''lntracranial Vascular Procedures with PDX Hemorrhage with CC or Epilepsy with Neurostimulator;'' or (2) reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain to another higher paying MS–DRG that would provide adequate reimbursement. The requestor stated its belief that MS–DRG 021 is a better fit in terms of average costs and clinical coherence for reassignment of RNS© System cases and recognized that there is likely still not enough volume to warrant the creation of new MS–DRGs for cases describing the insertion of the RNS© neurostimulator.

We first examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRG 023 and compared the results to cases representing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) that had a principal diagnosis of epilepsy in MS–DRG 023. The following table shows our findings:

MS-DRG 023	Number of Cases	Average Length of Stay	Average Costs
All cases	11,938	9.8	$40,264
Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	81	3.3	$52,362

As shown in the table, for MS–DRG 023, we identified a total of 11,938 cases, with an average length of stay of 9.8 days and average costs of $40,264. Of the 11,938 cases in MS–DRG 023, there were 81 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) that had a principal diagnosis of epilepsy with an average length of stay of 3.3 days and average costs of $52,362. Our clinical advisors reviewed these data, and agreed with the requestor that the number of cases is too small to warrant the creation of a new MS–DRG for these cases, for the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019).

We also examined the reassignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) to MS–DRGs 020, 021, and 022 (Intracranial Vascular Procedures with PDX Hemorrhage with MCC, with CC, and without CC/MCC, respectively). While the request was to reassign these cases to MS–DRG 021, MS–DRG 021 is specifically differentiated according to the presence of a secondary diagnosis with a severity level designation of a complication or comorbidity (CC). Cases with a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) do not always involve the presence of a secondary diagnosis with a severity level designation of a complication or comorbidity (CC), and therefore we reviewed data for all three MS–DRGs. The following table shows our findings:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
020	1,623	16.1	$75,668
021	409	12.3	$55,123
022	131	6.3	$35,599

As shown in the table, for MS–DRG 020, there were a total of 1,623 cases with an average length of stay of 16.1 days and average costs of $75,668. For MS–DRG 021, there were a total of 409 cases with an average length of stay of 12.3 days and average costs of $55,123. For MS–DRG 022, there were a total of 131 cases with an average length of stay of 6.3 days and average costs of $35,599.

We stated in the proposed rule that while the cases in MS–DRG 023 describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy have average costs that are similar to the average costs of cases in MS–DRG 021 ($52,362 compared to $55,123), they have an average length of stay that is 9 days shorter (3.3 days compared to 12.3 days), similar to our findings as summarized in the FY 2018 IPPS/LTCH PPS final rule. We stated that our clinical advisors reviewed the clinical issues and the claims data, and did not support reassigning the cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy from MS–DRG 023 to MS–DRGs 020, 021 or 022. As discussed in the FY 2018 IPPS/LTCH PPS final rule, the cases in MS–DRGs 020, 021 and 022 have a principal diagnosis of a hemorrhage. The RNS© neurostimulator generators are not used to treat patients with diagnosis of a hemorrhage. We stated our clinical advisors continue to believe that it is inappropriate to reassign cases representing a principal diagnosis of epilepsy to a MS–DRG that contains cases that represent the treatment of intracranial hemorrhage, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019). They also stated that the differences in average length of stay and average costs based on the more recent data continue to support this recommendation.

We then explored alternative options, as was requested. We noted that the 81 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy had an average length of stay of 3.3 days and average costs of $52,362, as compared to the 11,938 cases in MS–DRG 023 that had an average length of stay of 9.8 days and average costs of $40,264. While these neurostimulator cases had average costs that were $12,098 higher than the average costs of all cases in MS–DRG 023, there were only a total of 81 cases. There may have been other factors contributing to the higher costs.

We further analyzed the data to identify those cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), with at least one other procedure designated as an O.R. procedure, and a principal diagnosis of epilepsy. This approach can be useful in determining whether resource use is truly associated with a particular procedure or whether the procedure frequently occurs in cases with other procedures with higher than average resource use. Our data findings for MS–DRG 023 demonstrate that of the 81 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving

the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy, 19 reported at least one other procedure designated as an O.R. procedure, and had higher average costs ($72,995 versus $52,362) compared to the average costs of all cases in this subset of MS–DRG 023.

We also reviewed the cases reporting procedures describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy to identify the secondary diagnosis CC and/or MCC conditions reported in conjunction with these procedures that also may be contributing to the higher average costs for these cases. We reviewed the claims data to identify the number (frequency) and types of principal and secondary diagnosis CC and/or MCC conditions that were reported. Our findings for the cases reporting secondary diagnosis MCC and CC conditions, followed by the top 10 secondary diagnosis MCC and secondary diagnosis CC conditions that were reported within the claims data for this subset of cases are shown in the following tables:

MS-DRG 023: Principal diagnosis of epilepsy with neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into brain	Number of Cases	Average Length of Stay	Average Costs
With MCC	12	9.1	$69,213
With CC	44	6.9	$62,265

Top 10 Secondary Diagnosis MCC Conditions Reported with Procedure Code with a Neurostimulator Generator Inserted Into The Skull With The Insertion Of a Neurostimulator Lead Into The Brain and a Principal Diagnosis of Epilepsy

ICD-10-CM Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
G93.41	Metabolic encephalopathy	2	13	$89,413
G93.5	Compression of brain	2	15	$102,406
G93.6	Cerebral edema	2	9.5	$81,441
G80.0	Spastic quadriplegic cerebral palsy	1	2	$78,488
I62.1	Nontraumatic extradural hemorrhage	1	8	$25,946
I63.432	Cerebral infarction due to embolism of left posterior cerebral artery	1	2	$41,277
J69.0	Pneumonitis due to inhalation of food and vomit	1	10	$54,241
J96.00	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia	1	2	$29,846
J96.01	Acute respiratory failure with hypoxia	1	10	$54,241

Top 10 Secondary Diagnosis CC Conditions Reported with Procedure Code with a Neurostimulator Generator Inserted Into The Skull With The Insertion Of a Neurostimulator Lead Into The Brain and a Principal Diagnosis of Epilepsy

ICD-10-CM Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
E87.1	Hypo-osmolality and hyponatremia	5	3.4	$41,375
R47.01	Aphasia	4	6.8	$110,672
Z68.41	Body mass index (BMI) 40.0-44.9, adult	3	3.7	$39,620
F84.0	Autistic disorder	2	13.5	$47,357
G81.91	Hemiplegia, unspecified affecting right dominant side	2	15	$102,406
G97.61	Postprocedural hematoma of a nervous system organ or structure following a nervous system procedure	2	13	$89,413
R45.851	Suicidal ideations	2	8	$35,561
D68.9	Coagulation defect, unspecified	1	1	$39,700
D69.3	Immune thrombocytopenic purpura	1	1	$39,961
E22.2	Syndrome of inappropriate secretion of antidiuretic hormone	1	4	$12,705

While the results of the claims analysis as previously summarized indicate that the average costs of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy are higher compared to the average costs for all cases in their assigned MS–DRG, we stated in the proposed rule we could not ascertain from the claims data the resource use specifically attributable to the procedure during a hospital stay. These data show cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy, can present greater treatment difficulty, and have a need for additional intervention with other O.R. procedures. When reviewing consumption of hospital resources for this subset of cases, the claims data also clearly shows that the patients typically have multiple MCC and CC conditions, and the increased costs appear to be

attributable to the severity of illness of the patient.

In summary, we stated that we believe that further analysis of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy is needed prior to proposing any further reassignment of these cases to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped. We stated that we expected in future years, that we would have additional data that exhibit an increased number of cases that could be used to evaluate the potential reassignment of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy. Therefore, we did not propose to reassign cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) from MS–DRG 023 to MS–DRG 021. We also did not propose to reassign Responsive Neurostimulator (RNS©) System cases to another MS–DRG at this time.

Comment: Commenters agreed with CMS' proposal not to reassign cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) from MS–DRG 023 to MS–DRG 021 or to any another MS–DRG at this time. A commenter specifically thanked CMS for its consideration of addressing the costs and reimbursements associated with the insertion of the Responsive Neurostimulator (RNS©) System. Another commenter stated they appreciate CMS' willingness to continue to analyze the data, recognizing the discrepancy in average costs and the potential need for a MS–DRG assignment that provides adequate reimbursement.

Although supporting the decision to not reassign cases reporting the use of an RNS© System neurostimulator for epilepsy, a few commenters expressed concern that the average costs of these cases are higher than the average costs for all cases in the assigned MS–DRG 023 and stated their belief that the costs for the insertion of this device in traditional Medicare patients is not recouped. These same commenters acknowledged the issue is complex and beyond merely separating and reassigning neurostimulators for epilepsy. One commenter stated neurostimulator insertion for the treatment of epilepsy is not clinically similar to treatment of intracranial hemorrhage. Another commenter noted that complex neurostimulator implants may involve chronic disease states other than epilepsy, including Parkinson's disease and essential tremor and stated they agreed with CMS's decision to conduct further analyses, which would provide an opportunity to obtain additional stakeholder input related to improving MS–DRG assignments for neurostimulator procedures. Commenters noted that MS–DRGs 023 and 024 combine a wide range of principal diagnoses, procedures, and procedure approaches that could be contributing to the wide variation of costs of cases assigned to these MS–DRGs. Commenters proposed a number of ways CMS could attempt to create more homogenous groups and improve clinical cohesion such as (1) creating a new set of DRGs focused solely on the cost of the implantation of CNS devices that could be modeled after currently established MS–DRGs for the implantation of stents in carotid artery, stents in the coronary arteries or pacemakers, AICDs or other high-cost technologies in the heart, and/or (2) moving procedures assigned to MS–DRGs 023 and 024 that describe extirpation, drainage and removal to MS–DRGs 025, 026 and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively).

Response: We appreciate the commenters' feedback and support.

We also appreciate the commenters' suggestions regarding other potential changes to the current MS–DRG assignments for CMS's consideration. We continue to be attuned to the requestors' and commenters' concerns about reimbursement for cases describing the insertion of the RNS© neurostimulator. As part of our ongoing, comprehensive analysis of the MS–DRGs under ICD–10, we will continue to explore mechanisms to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped. Therefore, after consideration of the public comments we received, and for the reasons stated above, we are finalizing our proposal to maintain the assignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) in MS–DRG 023 in MDC 01.

4. MDC 3 (Diseases and Disorders of Ear, Nose and Throat): Temporomandibular Joint Replacements

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32484 through 32490), we discussed a request we received to consider reassignment of ICD–10–PCS procedure codes 0RRC0JZ (Replacement of right temporomandibular joint with synthetic substitute, open approach) and 0RRD0JZ (Replacement of left temporomandibular joint with synthetic substitute, open approach) from MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with and without CC/MCC, respectively) to MS–DRGs 131 and 132 (Cranial and Facial Procedures with and without CC/MCC, respectively) in MDC 03.

The requestor stated that it is inaccurate for procedure codes 0RRC0JZ and 0RRD0JZ that identify and describe replacement of the temporomandibular joint (TMJ), which involves excision of the TMJ followed by replacement with a prosthesis, to group to MS–DRGs 133 and 134 while excision of the TMJ alone, identified by procedure codes 0RBC0ZZ (Excision of right temporomandibular joint, open approach) and 0RBD0ZZ (Excision of left temporomandibular joint, open approach), groups to the higher weighted MS–DRGs 131 and 132. According to the requestor, reassignment of procedure codes 0RRC0JZ and 0RRD0JZ to the higher weighted MS–DRGs 131 and 132 is reasonable and the MS–DRG title of ''Cranial and Facial Procedures'' is more appropriate. However, the requestor also stated that the cost of the prosthesis would continue to be underpaid, despite that recommended reassignment. As an alternative option, the requestor suggested CMS analyze if there may be other higher weighted MS–DRGs that could more appropriately compensate providers for a TMJ replacement with prosthesis procedure.

In addition, the requestor recommended that we analyze all procedures involving the mandible and maxilla and consider reassignment of those procedure codes from MS–DRGs 129 (Major Head and Neck Procedures with CC/MCC or Major Device) and 130 (Major Head and Neck Procedures without CC/MCC) to MS–DRGs 131 and 132 because the codes describe procedures that are performed on facial and cranial structures. Finally, the requestor also suggested another option that included modifying the surgical hierarchy for MDC 03 by sequencing MS–DRGs 131 and 132 above MS–DRGs 129 and 130, which the requestor

asserted would provide for more appropriate payment to providers for the performance of multiple facial procedures.

In the proposed rule, we discussed these separate but related requests that involve procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133 and 134 in MDC 03.

As discussed in the proposed rule, in our analysis of the request involving temporomandibular joint replacements, we first identified the ICD–10–PCS procedure codes that describe the excision or replacement of a temporomandibular joint as shown in the following table.

ICD-10-PCS Code	Description
0RBC0ZZ	Excision of right temporomandibular joint, open approach
0RBC3ZZ	Excision of right temporomandibular joint, percutaneous approach
0RBC4ZZ	Excision of right temporomandibular joint, percutaneous endoscopic approach
0RBD0ZZ	Excision of left temporomandibular joint, open approach
0RBD3ZZ	Excision of left temporomandibular joint, percutaneous approach
0RBD4ZZ	Excision of left temporomandibular joint, percutaneous endoscopic approach
0RRC07Z	Replacement of right temporomandibular joint with autologous tissue substitute, open approach
0RRC0JZ	Replacement of right temporomandibular joint with synthetic substitute, open approach
0RRC0KZ	Replacement of right temporomandibular joint with nonautologous tissue substitute, open approach
0RRD07Z	Replacement of left temporomandibular joint with autologous tissue substitute, open approach
0RRD0JZ	Replacement of left temporomandibular joint with synthetic substitute, open approach
0RRD0KZ	Replacement of left temporomandibular joint with nonautologous tissue substitute, open approach

In the proposed rule we noted that the requestor is correct that procedure codes 0RRC0JZ and 0RRD0JZ that describe replacement of the right and left TMJ with a prosthesis (synthetic substitute) by an open approach group to MS–DRGs 133 and 134 and procedure codes 0RBC0ZZ and 0RBD0ZZ that describe excision of the right and left TMJ alone by an open approach group to the higher weighted MS–DRGs 131 and 132. We also noted that the corresponding related codes as previously listed in the table that describe different approaches (excision procedures) or different types of tissue substitute (replacement procedures) are also assigned to the same respective MS–DRGs.

We stated in the proposed rule that we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 133 and 134 to identify cases reporting ICD–10–PCS codes 0RRC0JZ or 0RRD0JZ. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
	All Cases	1,757	5.6	$15,337
133	0RRC0JZ or 0RRD0JZ	13	3.1	$21,677
	All Cases	849	2.5	$9,512
134	0RRC0JZ or 0RRD0JZ	23	2.1	$20,430

In MS–DRG 133, we found a total of 1,757 cases with an average length of stay of 5.6 days and average costs of $15,337. Of those 1,757 cases, there were 13 cases reporting ICD–10–PCS code 0RRC0JZ or 0RRD0JZ, with an average length of stay of 3.1 days and average costs of $21,677. In MS–DRG 134, we found a total of 849 cases with an average length of stay of 2.5 days and average costs of $9,512. Of those 849 cases, there were 23 cases reporting ICD–10–PCS code 0RRC0JZ or 0RRD0JZ, with an average length of stay of 2.1 days and average costs of $20,430. The analysis shows that cases reporting ICD–10–PCS procedure codes 0RRC0JZ or 0RRD0JZ in MS–DRGs 133 and 134 have higher average costs ($21,677 versus $15,337 and $20,430 versus $9,512, respectively) and shorter lengths of stay (3.1 days versus 5.6 days and 2.1 days versus 2.5 days, respectively) compared to all the cases in their assigned MS–DRG.

We also examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 131 and 132. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
131	1,181	5.4	$18,875
132	464	2.5	$11,558

In MS–DRG 131, we found a total of 1,181 cases with an average length of stay of 5.4 days and average costs of $18,875. In MS–DRG 132, we found a total of 464 cases with an average length of stay of 2.5 days and average costs of $11,558.

We stated in the proposed rule that overall, the data analysis shows that the average costs for the cases reporting procedure codes 0RRC0JZ and 0RRD0JZ in MS–DRGs 133 and 134 are more aligned with the average costs for all the cases in MS–DRG 131 ($21,677 and $20,430, respectively versus $18,875) compared to MS–DRG 132 where the average costs are not significantly different than the average costs of all the cases in MS–DRG 134 ($11,558 versus $9,512). We stated that our clinical advisors agreed that the replacement of a TMJ with prosthesis procedures (codes 0RRC0JZ or 0RRD0JZ) are more resource intensive and are clinically distinct from the cases reporting procedure codes 0RBC0ZZ and 0RBD0ZZ that involve excision of the TMJ alone. They also agreed that procedure codes 0RRC0JZ and 0RRD0JZ should be reassigned to a higher weighted MS–DRG. However, they recommended we conduct further claims analysis to identify if there are other MS–DRGs in MDC 03 where cases reporting these procedure codes may also be found and to compare that data.

As previously noted, the requestor had also recommended that we analyze all procedures involving the mandible and maxilla and consider reassignment of those procedure codes from MS–DRGs 129 and 130 to MS–DRGs 131 and 132. The requestor did not provide a specific list of the procedure codes involving the mandible and maxilla, therefore, we reviewed the list of procedure codes in MS–DRGs 129 and 130 and identified the following 26 procedure codes describing procedures performed on the mandible. There were no procedure codes describing procedures performed on the maxilla in MS–DRGs 129 and 130.

0NBT0ZZ	Excision of right mandible, open approach
0NBT3ZZ	Excision of right mandible, percutaneous approach
0NBT4ZZ	Excision of right mandible, percutaneous endoscopic approach
0NBV0ZZ	Excision of left mandible, open approach
0NBV3ZZ	Excision of left mandible, percutaneous approach
0NBV4ZZ	Excision of left mandible, percutaneous endoscopic approach
0NRT07Z	Replacement of right mandible with autologous tissue substitute, open approach
0NRT0JZ	Replacement of right mandible with synthetic substitute, open approach
0NRT0KZ	Replacement of right mandible with nonautologous tissue substitute, open approach
0NRT37Z	Replacement of right mandible with autologous tissue substitute, percutaneous approach
0NRT3JZ	Replacement of right mandible with synthetic substitute, percutaneous approach
0NRT3KZ	Replacement of right mandible with nonautologous tissue substitute, percutaneous approach
0NRT47Z	Replacement of right mandible with autologous tissue substitute, percutaneous endoscopic approach
0NRT4JZ	Replacement of right mandible with synthetic substitute, percutaneous endoscopic approach
0NRT4KZ	Replacement of right mandible with nonautologous tissue substitute, percutaneous endoscopic approach
0NRV07Z	Replacement of left mandible with autologous tissue substitute, open approach
0NRV0JZ	Replacement of left mandible with synthetic substitute, open approach
0NRV0KZ	Replacement of left mandible with nonautologous tissue substitute, open approach
0NRV37Z	Replacement of left mandible with autologous tissue substitute, percutaneous approach
0NRV3JZ	Replacement of left mandible with synthetic substitute, percutaneous approach
0NRV3KZ	Replacement of left mandible with nonautologous tissue substitute, percutaneous approach
0NRV47Z	Replacement of left mandible with autologous tissue substitute, percutaneous endoscopic approach
0NRV4JZ	Replacement of left mandible with synthetic substitute, percutaneous endoscopic approach
0NRV4KZ	Replacement of left mandible with nonautologous tissue substitute, percutaneous endoscopic approach
0NTT0ZZ	Resection of right mandible, open approach
0NTV0ZZ	Resection of left mandible, open approach

As noted in the proposed rule, based on the advice of our clinical advisors as previously discussed, we conducted additional analyses for MDC 03 using the same FY 2019 MedPAR data file and found cases reporting procedure code 0RRC0JZ or 0RRD0JZ for the replacement of a TMJ with prosthesis procedure in MS–DRGs 129, 130, 131, and 132. As discussed in section II.D.15. of the proposed rule and section II.E.15. of this final rule, cases with multiple procedures are assigned to the highest surgical class in the hierarchy to which one of the procedures is assigned. For example, if procedure code 0RRC0JZ which is assigned to the logic for MS–DRGs 133 and 134 is reported on a claim with procedure code 0NSR04Z (Reposition maxilla with internal fixation device, open approach), which

is assigned to the logic for MS–DRGs 131 and 132, the case will group to MS–DRG 131 or 132 (depending on the presence of a CC or MCC) when reported with a principal diagnosis from MDC 03 because MS–DRGs 131 and 132 are sequenced higher in the surgical hierarchy than MS–DRGs 133 and 134. Therefore, since MS–DRGs 129, 130, 131, and 132 are sequenced higher in the surgical hierarchy than MS–DRGs 133 and 134 in MDC 03, cases reporting procedure code 0RRC0JZ or 0RRD0JZ along with another O.R. procedure that is currently assigned to one of those MS–DRGs in the GROUPER logic results in case assignment to one of those higher surgical class MS–DRGs. We also identified cases reporting procedures performed on the mandible from the previously discussed list of procedure codes in MS–DRGs 129 and 130. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
129	All Cases	2,080	5.2	$18,091
	0RRC0JZ or 0RRD0JZ	3	3	$33,581
	Mandible Procedure	592	6.9	$21,258
130	All Cases	948	2.7	$11,092
	0RRC0JZ or 0RRD0JZ	5	3.4	$27,396
	Mandible Procedure	202	3.5	$14,712
131	All Cases	1,181	5.4	$18,875
	0RRC0JZ or 0RRD0JZ	4	7.3	$31,151
132	All Cases	464	2.5	$11,558
	0RRC0JZ or 0RRD0JZ	10	3.1	$24,099

As shown in the table, for MS–DRG 129, there was a total of 2,080 cases with average length of stay of 5.2 days and average costs of $18,091. Of these 2,080 cases, there were 3 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 3 days and average costs of $33,581 and 592 cases reporting a mandible procedure with average length of stay of 6.9 days and average costs of $21,258. For MS–DRG 130, there was a total of 948 cases with average length of stay of 2.7 days and average costs of $11,092. Of these 948 cases, there were there were 5 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 3.4 days and average costs of $27,396 and 202 cases reporting a mandible procedure with average length of stay of 3.5 days and average costs of $14,712. For MS–DRG 131, there was a total of 1,181 cases with average length of stay of 5.4 days and average costs of $18,875. Of these 1,181 cases there were 4 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 7.3 days and average costs of $31,151. For MS–DRG 132, there was a total of 464 cases with average length of stay of 2.5 days and average costs of $11,558. Of these 464 cases, there were 10 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 3.1 days and average costs of $24,099.

The data analysis demonstrates that the average costs of cases reporting procedure code 0RRC0JZ or 0RRD0JZ for the replacement of a TMJ with prosthesis procedure in MS–DRGs 129, 130, 131, and 132 and the cases reporting procedures performed on the mandible in MS–DRGs 129 and 130 have higher average costs compared to all the cases in their assigned MS–DRGs. While the volume of the cases reporting procedure code 0RRC0JZ or 0RRD0JZ was low with a total of 22 cases across MS–DRGs 129, 130, 131, and 132, similar to the analysis results for MS–DRGs 133 and 134 described earlier, the average costs for the cases are higher ($33,581 versus $18,091; $27,396 versus $11,092; $31,151 versus $18,875; and $24,099 versus $11,558) affirming that replacement of a TMJ with prosthesis procedures are more costly. The analysis also demonstrates that the average length of stay for cases reporting procedure code 0RRC0JZ or 0RRD0JZ across MS–DRGs 130, 131, and 132 is longer (3.4 days versus 2.7 days; 7.3 days versus 5.4 days; and 3.1 days versus 2.5 days) compared to all the cases in their assigned MS–DRGs. For MS–DRG 129, we found that the average length of stay was shorter (3 days versus 5.2 days) for cases reporting procedure code 0RRC0JZ or 0RRD0JZ. The data demonstrated similar results for the cases reporting procedures performed on the mandible in MS–DRGs 129 and 130, where the average costs for the cases are higher ($21,258 versus $18,091 and $14,712 versus $11,092, respectively) and the average length of stay was longer (6.9 days versus 5.2 days and 3.5 days versus 2.7 days, respectively) compared to all the cases in their assigned MS–DRG.

The analysis of MS–DRGs 129, 130, 131, and 132 further demonstrated that the average length of stay and average costs for all cases were almost identical for each of the subgroups. For example, MS–DRG 129 is defined as ''with CC/MCC or major device'' and MS–DRG 131 is defined as ''with CC/MCC'' while MS–DRGs 130 and 132 are both defined as ''without CC/MCC''. For all of the cases in MS–DRG 129, we found that the average length of stay was 5.2 days with an average cost of $18,091, and for all of the cases in MS–DRG 131, the average length of stay was 5.4 days with an average cost of $18,875. Similarly, for all of the cases in MS–DRG 130, we found that the average length of stay was 2.7 days with an average cost of $11,092, and for MS–DRG 132, we found the average length of stay was 2.5 days with an average cost of $11,558.

We noted in the proposed rule that as a result of the data analysis performed for MS–DRGs 129, 130, 131, and 132, including the analysis of the procedures describing replacement of a TMJ with prosthesis in MS–DRGs 133 and 134, as well as considering the requestor's suggestion that we examine the appropriateness of modifying the surgical hierarchy for MDC 03 by sequencing MS–DRGs 131 and 132

above MS–DRGs 129 and 130 to enable more appropriate payment for the performance of multiple facial procedures, our clinical advisors recommended evaluating all the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 to compare costs, complexity of service and clinical coherence to assess any potential reassignment of these procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 37, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software,* for complete documentation of the GROUPER logic for MS–DRGs 129, 130, 131, 132, 133, and 134.

As noted in the proposed rule, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting any of the procedure codes that are currently assigned to MS–DRGs 129, 130, 131, 132, 133, or 134. We refer the reader to Table 6P.2d associated with the proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/* for the detailed analysis. We note that if a procedure code that is currently assigned to MS–DRGs 129, 130, 131, 132, 133, or 134 is not displayed it is because there were no cases found reporting that code in the assigned MS–DRG.

The data analysis shows that there is wide variation in the volume, length of stay, and average costs of cases reporting procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134. There were several instances in which only one case was found to report a procedure code from MS–DRG 129, 130, 131, 132, 133, or 134, and the average length of stay for these specific cases ranged from 1 day to 31 days. For example, in MS–DRG 131, we found one case reporting procedure code 0NB70ZZ (Excision of occipital bone, open approach) with an average length of stay of 31 days which we consider to be an outlier in comparison to all the other cases reported in that MS–DRG with an average length of stay of 5.4 days. Overall, the average costs of cases in MS–DRGs 129 and 130 range from $4,970 to $38,217, the average costs of cases in MS–DRGs 131 and 132 range from $4,022 to $69,558 and the average costs of cases in MS–DRGs 133 and 134 range from $1,089 to $87,569. As noted previously, the data demonstrate there appear to be similar utilization of hospital resources specifically for cases reported in MS–DRGs 129, 130, 131 and 132.

The highest volume of cases was reported in MS–DRGs 129 and 130 for the procedure codes describing resection of the right and left neck lymphatic. For MS–DRG 129, there was a total of 750 cases reporting procedure code 07T10ZZ (Resection of right neck lymphatic, open approach) with an average length of stay of 4.7 days and average costs of $17,155 and there was a total of 679 cases reporting procedure code 07T20ZZ (Resection of left neck lymphatic, open approach) with an average length of stay of 4.8 days and average costs of $17,857. For MS–DRG 130, there was a total of 358 cases reporting procedure code 07T10ZZ with an average length of stay of 2.6 days and average costs of $10,432 and there was a total of 331 cases reporting procedure code 07T20ZZ with an average length of stay of 2.5 days and average costs of $10,467. For MS–DRGs 131 and 132, the highest volume of cases was reported for the procedure codes describing repositioning of the maxilla with internal fixation and repositioning of the right and left mandible with internal fixation. For MS–DRG 131, there was a total of 186 cases reporting procedure code 0NSR04Z (Reposition maxilla with internal fixation device, open approach) with an average length of stay of 5.1 days and average costs of $20,500; a total of 114 cases reporting procedure code 0NST04Z (Reposition right mandible with internal fixation device, open approach) with an average length of stay of 5.7 days and average costs of $18,710, and a total of 219 cases reporting procedure code 0NSV04Z (Reposition left mandible with internal fixation device, open approach) with an average length of stay of 6.0 days and average costs of $20,202. For MS–DRG 132, there was a total of 84 cases reporting procedure code 0NSR04Z with an average length of stay of 2.1 days and average costs of $12,991 and a total of 101 cases reporting procedure code 0NSV04Z with an average length of stay of 2.8 days and average costs of $11,386. For MS–DRGs 133 and 134, the highest volume of cases was reported for the procedure codes describing excision of the facial nerve or nasal turbinate. For MS–DRG 133, there was a total of 60 cases reporting procedure code 09BL8ZZ (Excision of nasal turbinate, via natural or artificial opening endoscopic) with an average length of stay of 6.6 days and average costs of $21,253 and for MS–DRG 134, there was a total of 50 cases reporting procedure code 00BM0ZZ (Excision of facial nerve, open approach) with an average length of stay of 1.4 days and average costs of $8,048.

Our clinical advisors reviewed the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 to identify the patient attributes that currently define each of these procedures and to group them with respect to complexity of service and resource intensity. For example, procedures that we believe represent greater treatment difficulty and reflect a class of patients who are similar clinically with regard to consumption of hospital resources were grouped separately from procedures that we believe to be less complex but still reflect patients who are similar clinically with regard to consumption of hospital resources. This approach differentiated the more complex and invasive procedures, such as resection of cervical lymph nodes, repositioning of facial bones, and excision of mandible procedures from the less complex and less invasive procedures such as excisions (biopsies) of lymph nodes and facial nerves, drainage procedures of the upper respiratory system, and tonsillectomies.

We stated in the proposed rule that after this comprehensive review of all the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134, in combination with the results of the data analysis discussed previously, our clinical advisors support distinguishing the procedures currently assigned to those MS–DRGs by clinical intensity, complexity of service and resource utilization and also support restructuring of these MS–DRGs accordingly. We noted that during the analysis of the procedures currently assigned to MS–DRGs 129 and 130, we recognized the special logic defined as ''Major Device Implant'' for MS–DRG 129 that identifies procedures describing the insertion of a cochlear implant or other hearing device. We stated that our clinical advisors supported the removal of this special logic from the definition for assignment to any modifications to the MS–DRGs, noting the costs of the device have stabilized over time and the procedures can be appropriately grouped along with other procedures involving devices in any restructured MS–DRGs. We also identified 2 procedure codes currently assigned to MS–DRGs 131 and 132, 00J00ZZ (Inspection of brain, open approach) and 0WJ10ZZ (Inspection of cranial cavity, open approach), that our clinical advisors agreed should not be included in any modifications to the MS–DRGs in MDC 03, stating that they are appropriately assigned to MS–DRGs

in MDC 01 (Diseases and Disorders of the Nervous System). We further noted that during our analysis of the procedures currently assigned to MS–DRGs 133 and 134, we found 338 procedure codes that were inadvertently included as a result of replication during our transition from the ICD–9 to ICD–10 based MS–DRGs. We referred the reader to Table 6P.2c associated with the proposed rule for a detailed list of these procedure codes that describe procedures performed on various sites, such as the esophagus, stomach, intestine, skin, and thumb that we stated our clinical advisors agree should be removed from the definition for assignment to any modifications to the MS–DRGs under MDC 03.

As a result of our review, we proposed the deletion of MS–DRGs 129, 130, 131, 132, 133, and 134, and the creation of six new MS–DRGs. Currently, MS–DRGs 129, 131, and 133 are defined as base MS–DRGs, each of which is split by a two-way severity level subgroup. Our proposal includes the creation of two new base MS–DRGs with a three-way severity level split. As discussed in the proposed rule, our clinical advisors suggested that based on the analysis of procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 as described previously, only 2 base MS–DRGs were needed, each divided into 3 levels according to the presence of a CC or MCC. The MS–DRGs were developed consistent with the analysis to differentiate the more complex and invasive procedures from the less complex and less invasive procedures. As noted previously, our analysis of MS–DRGs 129, 130, 131, and 132 demonstrated that the average length of stay and average costs for all cases were almost identical for each of the severity level subgroups and therefore, the procedures assigned to these MS–DRGs were initially reviewed together as one clinical group and then evaluated further in comparison to the procedures currently assigned to MS–DRGs 133 and 134. The objective was to better differentiate procedures by treatment difficulty, clinical similarity, and resource use, and to propose a more appropriate restructuring. For example, based on this analysis, in some instances, we proposed to reassign procedures described by procedure codes that are currently assigned to MS–DRGs 129 and 130 or MS–DRGs 131 and 132 to what is being defined as the less complex MS–DRGs. We stated that we believe the resulting MS–DRG assignments are more clinically homogeneous, coherent and better reflect hospital resource use.

We applied the criteria to create subgroups for the three-way severity level split for the proposed new MS–DRGs and found that all five criteria were met. We stated that for the proposed new MS–DRGs, there is at least (1) 500 cases in the MCC group, the CC group and the NonCC group; (2) 5 percent of the cases in the MCC group, the CC group and the NonCC group; (3) a 20 percent difference in average costs between the MCC group, the CC group and the NonCC group; (4) a $2,000 difference in average costs between the MCC group, the CC group and the NonCC group; and (5) a 3-percent reduction in cost variance, indicating that the severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. The following table reflects our simulation for the proposed new MS–DRGs with a three-way severity level split. We stated that our findings represent what we would expect under the proposed modifications and proposed new MS–DRGs, based on claims data in the FY 2019 MedPAR file.

New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
New MS-DRG 140 Major Head and Neck Procedures with MCC	620	9.1	$29,441
New MS-DRG 141 Major Head and Neck Procedures with CC	2,349	4.4	$16,229
New MS-DRG 142 Major Head and Neck Procedures without CC/MCC	1,273	2.7	$11,816
New MS-DRG 143 Other Ear, Nose, Mouth, and Throat O.R. Procedures with MCC	631	7.9	$20,126
New MS-DRG 144 Other Ear, Nose, Mouth, and Throat O.R. Procedures with CC	1,414	4.3	$12,523
New MS-DRG 145 Other Ear, Nose, Mouth, and Throat O.R. Procedures without CC/MCC	986	2.4	$9,026

We proposed to create two new base MS–DRGs, 140 and 143, with a three-way severity level split for proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and proposed new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

We referred the reader to Table 6P. 2a and Table 6P.2b associated with the proposed rule for the list of procedure codes we proposed for reassignment from MS–DRGs 129, 130, 131, 132, 133, and 134 to each of the new MS–DRGs. As noted, we also proposed the removal of procedure codes 00J00ZZ and 0WJ10ZZ, and the 338 procedure codes listed in Table 6P. 2c associated with the proposed rule from the logic for MDC 03.

Comment: Commenters generally agreed with the proposal to delete MS–DRGs 129, 130, 131, 132, 133, and 134, and to create proposed new MS–DRGs 140, 141, and 142 under proposed new base MS–DRG 140, and to create proposed new MS–DRGs 143, 144, and 145 under proposed new base MS–DRG 143, however, the commenters recommended CMS review the list of proposed procedure codes for assignment to the proposed new MS–DRGs. A commenter noted that procedure codes describing reposition of the left temporal bone were included in Table 6P.2a and proposed for assignment to MS–DRGs 140,141, and 142 while procedure codes describing reposition of the right temporal bone were included in Table 6P.2b and proposed for assignment to MS–DRGs 143, 144, and 145. The commenter also

stated their belief that CMS should classify all repositions of occipital, temporal, frontal and other bones of the skull as major surgery and assign them to proposed new MS–DRGs 140, 141, and 142. The commenter provided the following ICD–10–PCS procedure codes for CMS' consideration.

ICD-10-PCS Code	Description
0NS004Z	Reposition skull with internal fixation device, open approach
0NS005Z	Reposition skull with external fixation device, open approach
0NS00ZZ	Reposition skull, open approach
0NS034Z	Reposition skull with internal fixation device, percutaneous approach
0NS035Z	Reposition skull with external fixation device, percutaneous approach
0NS03ZZ	Reposition skull, percutaneous approach
0NS044Z	Reposition skull with internal fixation device, percutaneous endoscopic approach
0NS045Z	Reposition skull with external fixation device, percutaneous endoscopic approach
0NS04ZZ	Reposition skull, percutaneous endoscopic approach
0NS304Z	Reposition right parietal bone with internal fixation device, open approach
0NS30ZZ	Reposition right parietal bone, open approach
0NS334Z	Reposition right parietal bone with internal fixation device, percutaneous approach
0NS33ZZ	Reposition right parietal bone, percutaneous approach
0NS344Z	Reposition right parietal bone with internal fixation device, percutaneous endoscopic approach
0NS34ZZ	Reposition right parietal bone, percutaneous endoscopic approach
0NS404Z	Reposition left parietal bone with internal fixation device, open approach
0NS40ZZ	Reposition left parietal bone, open approach
0NS434Z	Reposition left parietal bone with internal fixation device, percutaneous approach
0NS43ZZ	Reposition left parietal bone, percutaneous approach
0NS444Z	Reposition left parietal bone with internal fixation device, percutaneous endoscopic approach
0NS44ZZ	Reposition left parietal bone, percutaneous endoscopic approach
0NS504Z	Reposition right temporal bone with internal fixation device, open approach
0NS50ZZ	Reposition right temporal bone, open approach
0NS534Z	Reposition right temporal bone with internal fixation device, percutaneous approach
0NS53ZZ	Reposition right temporal bone, percutaneous approach
0NS544Z	Reposition right temporal bone with internal fixation device, percutaneous endoscopic approach
0NS54ZZ	Reposition right temporal bone, percutaneous endoscopic approach
0NSM0ZZ	Reposition right zygomatic bone, open approach
0NSN0ZZ	Reposition left zygomatic bone, open approach
0NSR05Z	Reposition maxilla with external fixation device, open approach

Another commenter stated there is not a clear understanding of the scope of the proposed changes because the MedPAR data included in the proposed rule referred to temporomandibular joint replacements; however, the procedure listing for the MS–DRGs extended beyond those procedures. The commenter stated that tables 6P.2a and

6P.2b associated with the proposed rule include procedures on vessels, lymphatic and other organs in the head and neck. The commenter stated the procedures noted in the tables cross multiple MS–DRGs such as 853, 857, 856, 571, 264, 570, 463, and 902 which were not discussed in the proposed rule. The commenter requested that CMS provide clarity on this topic.

A commenter acknowledged that CMS proposed removing a number of ICD–10–PCS procedure codes from the MDC 03 logic that had been inadvertently included as a result of replication during the transition from ICD–9- to ICD–10-based MS–DRGs. However, according to the commenter there are additional procedure codes not included on CMS' list shown in table 6P.2c that should also be removed from the MDC 03 logic. The commenter noted an example of where some codes for procedures on the esophagus have been proposed for removal from the MDC 03 logic, while other procedures performed on the esophagus are still proposed for inclusion in the GROUPER logic. The commenter also noted that procedures performed on the heart, carotid artery, chest, back abdomen, buttock, liver, and leg are not ear, nose, mouth, or throat procedures, but they are included in the proposed GROUPER logic for proposed new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter stated that procedures on the chest, back, and abdomen are not head or neck procedures, but they are included in the proposed GROUPER logic for proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively). In addition, the commenter stated that while CMS proposed reassigning procedure code 0WJ10ZZ (Inspection of cranial cavity, open approach) from MDC 03 (Diseases and Disorders of Ear, Nose and Throat) to MDC 01 (Diseases and Disorders of the Nervous System), codes for other procedures performed on the cranial cavity are proposed to be included in the GROUPER logic for proposed new MS–DRGs 140, 141, and 142. The commenter recommended that CMS review the procedure codes listed in tables 6P.2a and 6P.2b to identify all of the procedure codes that should be removed from the GROUPER logic for proposed new MS–DRGs 140, 141, 142, 143, 144, and 145. Lastly, the commenter suggested that CMS consider whether proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) belong in MDC 03 or whether the title of the MDC should be changed since, according to the commenter, the MDC 03 description ''Diseases and Disorders of Ear, Nose and Throat'' covers a more limited set of anatomic sites than the ''major head and neck procedures'' included in proposed new MS–DRGs 140, 141, and 142.

Response: We thank the commenters for their support of the proposal to create two new base MS–DRGs, 140 and 143, with a three-way severity level split for new MS–DRGs 140, 141, and 142 and new MS–DRGs 143, 144, and 145. We appreciate the commenter noting that some procedure codes describing reposition of the left temporal bone were included in Table 6P.2a and proposed for assignment to proposed new MS–DRGs 140, 141, and 142, while procedure codes describing reposition of the right temporal bone were included in Table 6P.2b and proposed for assignment to proposed new MS–DRGs 143, 144, and 145. We note that this was an inadvertent error, and the procedure codes describing reposition of the left temporal bone that were included in Table 6P.2a were intended to be included in Table 6P.2b with the codes describing reposition of the right temporal bone, as both sets of codes were intended to be proposed for reassignment to proposed new MS–DRGs 143, 144, and 145 because they describe procedures that are considered to be less complex and less invasive compared to the procedures proposed for reassignment to proposed new MS–DRGs 140, 141, and 142 that describe more complex and more invasive procedures. In response to the commenter's recommendation to classify all repositions of occipital, temporal, frontal and other bones of the skull as major surgery and assign them to proposed new MS–DRGs 140, 141, and 142, our clinical advisors do not agree. In the comprehensive review of all the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134, which involved an analysis of claims data and clinical judgment, they identified and separated out the procedures they believed to be more clinically complex and resource intensive and those are the procedures that were proposed to be reassigned to proposed new MS–DRGs 140, 141, and 142 so that payment rates are better aligned. Therefore, with respect to the procedure codes describing reposition of temporal, frontal and other bones of the skull identified by the commenter, our clinical advisors do not believe these procedures reflect the complexity or resource utilization consistent with the other procedure codes proposed for reassignment to proposed new MS–DRGs 140, 141, and 142 because they are considered to be less complex and less resource intensive. We note that while the commenter suggested CMS review the procedure codes describing reposition of the occipital bone, it did not include any of those procedure codes for CMS' consideration in its list. We further note that procedure codes describing reposition of the occipital bone were already proposed to be reassigned to proposed new MS–DRGs 140, 141, and 142 as displayed in table 6P.2a associated with the proposed rule, therefore we are unclear as to which procedure codes involving the occipital bone the commenter is specifically referring to.

In response to the commenter who stated there is not a clear understanding of the scope of the proposed changes because the MedPAR data included in the proposed rule referred to other procedure codes in addition to the procedure code for temporomandibular joint replacements, we note that as discussed in the proposed rule (85 FR 32484 through 32490), this was a multi-part request involving the reassignment of ICD–10–PCS procedure codes 0RRC0JZ and 0RRD0JZ that describe replacement of the right and left temporomandibular joint from MS–DRGs 133 and 134 to MS–DRGs 131 and 132, the reassignment of the procedures involving the mandible and maxilla identified with procedure codes from MS–DRGs 129 and 130 to MS–DRGs 131 and 132, and modifying the surgical hierarchy for MS–DRGs 131, 132, 133, and 134. We stated that we examined claims data for all the procedures identified by procedure codes currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 and we provided our claims analysis in Table 6P.2d associated with the proposed rule as well as discussion of our analysis and the basis for our proposals. In response to the comments regarding Tables 6P.2a and 6P.2b that included proposals for procedure codes describing procedures on vessels, lymphatic and other organs in the head and neck across multiple MS–DRGs such as 853, 857, 856, 571, 264, 570, 463, and 902 we note that this is because certain procedure codes are currently assigned to multiple MDCs and MS–DRGs as shown in Appendix E-Operating Room Procedures and Procedure Code/MS–DRG Index of the ICD–10 MS–DRGs Definitions Manual. For example, procedure code 07B00ZZ (Excision of head lymphatic, open approach) which is listed in Table

6P.2b, is currently assigned to the following MDCs and MS–DRGs.

ICD-10-PCS Code	MDC	MS-DRG	Description
07B00ZZ	03	133-134	Other Ear, Nose, Mouth and Throat O.R. Procedures
	09	579-581	Other Skin, Subcutaneous Tissue and Breast Procedures
	16	802-804	Other O.R. Procedures of the Blood and Blood Forming Organs
	17	820-822	Lymphoma and Leukemia with Major Procedure
	17	826-828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure

We encourage the commenter to review Appendix E of the ICD–10 MS–DRG Definitions Manual for further clarification and understanding of how each procedure code may be assigned to multiple MDCs and MS–DRGs under the IPPS.

In response to the commenter who stated their belief that there are additional codes that should also be removed from the MDC 03 logic, such as other procedures performed on the esophagus that were proposed to be included in the GROUPER logic, and procedures performed on the heart, carotid artery, chest, back abdomen, buttock, liver, and leg that are not ear, nose, mouth, or throat procedures, but were included in the proposed GROUPER logic for MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), we note that, as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The other classes would include diagnoses or procedures which were infrequently encountered or not well defined clinically. For example, the ''other'' medical class for the Respiratory System MDC would contain the diagnoses ''other somatoform disorders'' and ''congenital malformation of the respiratory system,'' while the ''other'' surgical class for the female reproductive MDC would contain the surgical procedures ''excision of liver'' (liver biopsy in ICD–9–CM) and ''inspection of peritoneal cavity'' (exploratory laparotomy in ICD–9–CM). The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. There are, however, also patients who receive surgical procedures which are completely unrelated to the MDC to which the patient was assigned. An example of such a patient would be a patient with a principal diagnosis of pneumonia whose only surgical procedure is a destruction of prostate (transurethral prostatectomy in ICD–9–CM). Such patients are assigned to a surgical class referred to as ''unrelated operating room procedures.'' These patients are ultimately never assigned to a well-defined DRG.'' With regard to the comment that procedures on the chest, back, and abdomen were included in the proposed GROUPER logic for proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively), we note that the commenter did not provide the specific procedure codes for CMS to review and therefore we were unable to evaluate the commenter's concerns for FY 2021, however, we will take these comments under consideration for future rulemaking. In response to the commenter's statement that codes for other procedures performed on the cranial cavity were proposed to be included in the GROUPER logic for proposed new MS–DRGs 140, 141, and 142, we note that the logic for proposed new MS–DRGs 140, 141, and 142 is comprised of a subset of procedure codes describing procedures performed on the cranial cavity that are currently assigned to MS–DRGs 131 and 132 (Cranial and Facial Procedures with and without CC/MCC, respectively). Our clinical advisors reviewed the list of procedures currently assigned to those MS–DRGs and believed that procedure codes 00J00ZZ and 0WJ10ZZ could be removed from the logic based on the analysis of all the procedure codes and because these codes are currently assigned to MS–DRGs in MDC 01 which they stated is clinically more appropriate. With respect to the commenter's suggestion that CMS consider whether proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) belong in MDC 03 or whether the title of the MDC should be changed since, according to the commenter, the MDC 03 description ''Diseases and Disorders of Ear, Nose and Throat'' covers a more limited set of anatomic sites than the ''major head and neck procedures'' included in proposed new MS–DRGs 140, 141, and 142, we will take this under consideration for future rulemaking.

After consideration of the comments we received, we are finalizing our proposal to create two new base MS–DRGs, 140 and 143, with a three-way severity level split for new MS–DRGs 140, 141, and 142 and new MS–DRGs 143, 144, and 145 and we are also finalizing our proposal to delete MS–

DRGs 129, 130, 131, 132, 133, and 134 for FY 2021. We refer the reader to Tables 6P.2a, 6P.2b, and 6P.2c associated with this final rule and available via the internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for the finalized list of procedure codes that define the logic for the finalized MS–DRGs. We note that discussion of the surgical hierarchy for the modifications is discussed in section II.E.15. of this final rule.

5. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Left Atrial Appendage Closure (LAAC)

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49363 through 49367), we finalized our proposal to create two new MS–DRGs to classify percutaneous intracardiac procedures. Specifically, we created MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectfully) for cases reporting procedure codes describing cardiac ablation and other percutaneous intracardiac procedures. In that discussion, as FY 2016 was the first year of our transition from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs, we provided a list of the ICD–9–CM procedure codes that identify and describe the cardiac ablation procedures and other percutaneous intracardiac procedures that were the subject of that MS–DRG classification change request, one of which was ICD–9–CM procedure code 37.90 (Insertion of left atrial appendage device).

Separately, we also discussed a request that we received for new technology add-on payments for the WATCHMAN™ Left Atrial Appendage Closure (LAAC) device (80 FR 49480 through 49488). In that discussion, we noted that effective October 1, 2004 (FY 2005), ICD–9–CM procedure code 37.90 (Insertion of left atrial appendage device) was created to identify and describe procedures using the WATCHMAN™ Left Atrial Appendage (LAA) Closure Technology and that under ICD–10–PCS, procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) is the comparable translation. We also noted that at the time of the new technology request, under the ICD–9 based MS–DRGs, procedure code 37.90 was assigned to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC and without MCC, respectively). We further noted that, as stated previously, we finalized our proposal to assign procedures performed within the heart chambers using intracardiac techniques, including those identified by ICD–9–CM procedure code 37.90, and its comparable ICD–10–PCS code translations (that specifically identify a percutaneous or percutaneous endoscopic approach), including 02L73DK, to new MS–DRGs 273 and 274.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32490 through 324950), we received two separate, but related requests involving the procedure codes that describe the technology that is utilized in the performance of LAAC procedures. The first request was to reassign ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) that identifies the WATCHMAN™ Left Atrial Appendage Closure (LAAC) device, from MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) to MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC) and revise the title for MS–DRG 273 to ''Percutaneous Intracardiac Procedures with MCC or Major Device Implant for Left Atrial Appendage Closure Procedures''. As stated in the proposed rule, cases involving LAAC procedures with a percutaneous or percutaneous endoscopic approach, including cases reporting ICD–10–PCS procedure code 02L73DK, are currently assigned to MS–DRGs 273 and 274.

We stated in the proposed rule that according to the requestor's analysis, the average cost for LAAC procedures reporting ICD–10–PCS procedure code 02L73DK is $3,405 higher than the average cost for all cases in MS–DRG 274. The requestor stated that based on its analysis, this requested reassignment would have minimal impact on MS–DRGs 273 and 274 and would ensure adequate payments and better resource coherency. The requestor stated that cases reporting procedure codes describing a LAAC procedure with procedure code 02L73DK within MS–DRG 274 are more clinically similar and costs are more closely aligned to cases within MS–DRG 273.

As indicated in the proposed rule, in response to the first request, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 273 and 274 to identify cases reporting ICD–10–PCS procedure code 02L73DK. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
273	All Cases	7,048	6.1	$28,100
	02L73DK	1,126	2.7	$29,504
274	All Cases	24,319	2.0	$24,048
	02L73DK	13,423	1.2	$25,846

In MS–DRG 273, we found a total of 7,048 cases with an average length of stay of 6.1 days and average costs of $28,100. Of those 7,048 cases, there were 1,126 cases reporting ICD–10–PCS procedure code 02L73DK, with an average length of stay of 2.7 days and average costs of $29,504. In MS–DRG 274, we found a total of 24,319 cases with an average length of stay of 2.0 days and average costs of $24,048. Of those 24,319 cases, there were 13,423 cases reporting ICD–10–PCS procedure code 02L73DK, with an average length of stay of 1.2 days and average costs of $25,846.

The data analysis demonstrates that the average costs of the cases reporting procedure code 02L73DK in MS–DRG 274 are slightly higher than the average costs of all the cases in MS–DRG 274 ($25,846 versus $24,048), with a difference of approximately $1,798, however, the average length of stay for cases reporting procedure code 02L73DK in MS–DRG 274 is shorter compared to all the cases in MS–DRG

274 (1.2 days versus 2 days). We stated in the proposed rule that if we were to reassign cases reporting procedure code 02L73DK from MS–DRG 274 to MS–DRG 273, we would be assigning cases with an average length of stay of 1.2 days to a MS–DRG with an average length of stay of 6.1 days, which our clinical advisors did not support. As indicated in the proposed rule, the average costs of the cases reporting procedure code 02L73DK in MS–DRG 274 ($25,846) compared to the average costs of all the cases in MS–DRG 273 ($28,100) show a difference of $2,254. We stated in the proposed rule that our clinical advisors did not support reassigning the 13,423 cases reporting procedure code 02L73DK without an MCC from MS–DRG 274 to MS–DRG 273, which includes cases reporting a MCC, noting that it would impact the average costs for all cases in this MS–DRG. Lastly, as stated in the proposed rule, our clinical advisors expressed concern regarding making MS–DRG changes based on a specific, single technology (WATCHMAN™ Left Atrial Appendage Closure (LAAC) device), identified by only one unique procedure code versus considering changes based on a group of related procedure codes that can be reported to describe that same type or class of technology, which is more consistent with the intent of the MS–DRGs. Therefore, for these reasons, we did not propose to reassign cases reporting ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) from MS–DRG 274 to MS–DRG 273.

In the proposed rule we also discussed a second request that we received to create a new MS–DRG specific to all left atrial appendage closure (LAAC) procedures or to map all LAAC procedures to a different cardiovascular MS–DRG that has payment rates aligned with procedural costs. The requestor stated that by creating a new MS–DRG specific to all LAAC procedures or mapping all LAAC procedures to a different cardiovascular MS–DRG, the MS–DRG would more appropriately recognize the clinical characteristics and cost differences in LAAC cases.

The 9 ICD–10–PCS procedure codes that describe LAAC procedures and their corresponding MS–DRG assignment are listed in the following table.

ICD-10-PCS Code	MS-DRG	Description
02L70CK	250-251	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	250-251	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	250-251	Occlusion of left atrial appendage, open approach
02L73CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	273-274	Occlusion of left atrial Appendage with intraluminal device, percutaneous approach
02L73ZK	273-274	Occlusion of left atrial appendage, percutaneous approach
02L74CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	273-274	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	273-274	Occlusion of left atrial appendage, percutaneous endoscopic approach

Currently, the MS–DRG assignments for these procedure codes are based on the surgical approach: open approach, percutaneous approach, or percutaneous endoscopic approach. Procedures describing an open approach are assigned to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with and without MCC, respectively); while procedures describing a percutaneous or percutaneous endoscopic approach are assigned to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectfully). Of the nine listed ICD–10–PCS procedure codes, three (02L70CK, 02L70DK, and 02l70ZK) describe an open approach and are currently assigned to MS–DRG 250 and 251, and six (02L73CK, 02L73DK, 02L73ZK, 02L74CK, 02L74DK, 02L74ZK) describe a percutaneous or percutaneous endoscopic approach and are currently assigned to MS–DRG 273 and 274.

As indicated in the proposed rule, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting LAAC procedures with an open approach in MS–DRGs 250 and 251. Our findings are shown in the following table.

MS-DRGs 250 and 251 - LAAC Procedures with Open Approach				
MS-DRG	**ICD-10-PCS Code**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
250	All Cases	4,192	5.0	$18,807
	LAAC procedures with open approach	21	7.0	$44,012
251	All Cases	4,941	2.6	$12,535
	LAAC procedures with open approach	74	3.4	$22,711

In MS–DRG 250, we found a total of 4,192 cases with an average length of stay of 5.0 days and average costs of $18,807. Of those 4,192 cases, there were 21 cases reporting a LAAC procedure with an open approach, with an average length of stay of 7.0 days and average costs of $44,012. In MS–DRG 251, we found a total of 4,941 cases with an average length of stay of 2.6 days and average costs of $12,535. Of those 4,941 cases, there were 74 cases reporting a LAAC procedure with an open approach, with an average length of stay of 3.4 days and average costs of $22,711. The analysis shows that the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 have higher average costs compared to all cases in MS–DRGs 250 and 251 ($44,012 versus $18,807 and $22,711 versus $12,535, respectively). The analysis also shows that the average length of stay for cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 is longer compared to all cases in MS–DRGs 250 and 251 (7.0 days versus 5.0 days and 3.4 days versus 2.6 days, respectively). Overall, there were a total of 95 (21+74) cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 with an average length of stay of 4.2 days and average costs of $27,420. Based on the results of the claims data described previously, we conducted further analysis for the 95 cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 to determine if there were additional factors that may be contributing to the higher average costs and longer length of stay. Of those 95 cases, we found a total of 20 cases in which there was another O.R. procedure reported on the claim that is also currently assigned to MS–DRGs 250 and MS–DRG 251 and believed to be influencing the average costs and average length of stay, as shown in the following tables.

MS-DRG 250
List of O.R. Procedures Reported with LAAC Procedure (02L70CK, 02L70DK or 02L70ZK)

ICD-10-PCS Code	Description	Number of Cases	Average Length of Stay	Average Costs
02UX0JZ	Supplement thoracic aorta, ascending/arch with synthetic substitute, open approach	2	10.0	$62,770
04U00JZ	Supplement abdominal aorta with synthetic substitute, open approach	1	7.0	$20,650
06H03DZ	Insertion of intraluminal device into inferior vena cava, percutaneous approach	1	4.0	$22,837
06JY4ZZ	Inspection of lower vein, percutaneous endoscopic approach	1	4.0	$20,772
0BNL4ZZ	Release left lung, percutaneous endoscopic approach	1	12.0	$55,375
0JH602Z	Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach	1	9.0	$28,333
0WJC0ZZ	Inspection of mediastinum, open approach	1	15.0	$235,720
	Total	8	8.9	$63,653

As shown in the table, for MS–DRG 250, there were a total of 8 cases reporting another O.R. procedure with a LAAC procedure with an open approach with an average length of stay of 8.9 days and average costs of $63,653. The data shows that the average length of stay for these 8 cases range from 4.0 days to 15.0 days and the average costs range from $20,650 to $235,720.

As indicated in the proposed rule, overall, the data demonstrates that the 8 cases reporting another O.R. procedure with a LAAC procedure with an open approach in MS–DRG 250 have a longer length of stay (8.9 days versus 7 days) and higher average costs ($63,653 versus $44,012) compared to all 21 cases reporting a LAAC procedure with an open approach in MS–DRG 250.

MS-DRGs 251 List of O.R. Procedures Reported with LAAC Procedure (02L70CK, 02L70DK or 02L70ZK)				
ICD-10-PCS Code	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
01580ZZ	Destruction of thoracic nerve, open approach	1	1.0	$16,648
015L0ZZ	Destruction of thoracic sympathetic nerve, open approach	1	3.0	$34,074
02JA0ZZ	Inspection of heart, open approach	2	7.0	$39,326
02JA4ZZ	Inspection of heart, percutaneous endoscopic approach	1	4.0	$17,070
02JY0ZZ	Inspection of great vessel, open approach	1	5.0	$21,002
02PA0MZ	Removal of cardiac lead from heart, open approach	1	2.0	$12,767
02S00ZZ	Reposition coronary artery, one artery, open approach	1	11.0	$89,682
03UL0KZ	Supplement left internal carotid artery with nonautologous tissue substitute, open approach	1	9.0	$20,229
0BNP0ZZ	Release left pleura, open approach	1	18.0	$40,720
0W3D0ZZ	Control bleeding in pericardial cavity, open approach	1	9.0	$36,820
0WJC4ZZ	Inspection of mediastinum, percutaneous endoscopic approach	1	2.0	$11,052
	Total	12	6.5	$31,560

As shown in the table, for MS–DRG 251, there were a total of 12 cases reporting another O.R. procedure with a LAAC procedure with an open approach with an average length of stay of 6.5 days and average costs of $31,560. The data shows that the average length of stay for these 12 cases range from 1.0 day to 18.0 days and the average costs range from $11,052 to $89,682.

As indicated in the proposed rule, the data demonstrates that the 12 cases reporting another O.R. procedure with a LAAC procedure with an open approach in MS–DRG 251 have a longer average length of stay (6.5 days versus 3.4 days) and higher average costs ($31,560 versus $22,711) compared to all 74 cases reporting a LAAC procedure with an open approach in MS–DRG 251. The results of our claims analysis for the 20 cases reporting a LAAC procedure with an open approach and another O.R. procedure in MS–DRGs 250 and 251 indicate that the longer average length of stay and higher average costs of the 95 cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 may be attributed to the resource consumption of the additional O.R. procedures reported in the subset of 20 cases. The claims analysis also shows that the majority of the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 (75 cases out of 95 cases) were without another O.R. procedure.

As noted previously, with respect to the first LAAC MS–DRG request, our analysis of MS–DRG 273 found a total of 7,048 cases with an average length of stay of 6.1 days and average costs of $28,100 and our analysis of MS–DRG 274 found a total of 24,319 cases with an average length of stay of 2.0 days and average costs of $24,048. The average costs and average length of stay for cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 ($44,012 and $22,711, respectively) and (7.0 days and 3.4 days, respectively) appear to be generally more aligned with the average costs and average length of stay for all cases in MS–DRGs 273 and 274 ($28,100 and $24,048, respectively) and (6.1 days and 2.0 days, respectively) as compared to all cases in MS–DRGs 250 and 251 with average costs of $18,807 and $12,535, respectively and an average length of stay of 5.0 days and 2.6 days, respectively. In addition, as also noted previously, the second LAAC MS–DRG request was to create a new MS–DRG specific to all left atrial appendage closure (LAAC) procedures or to map all LAAC procedures to a different cardiovascular MS–DRG that has payment rates aligned with procedural costs. We stated in the proposed rule that our clinical advisors suggested that because our review of the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 demonstrated that these procedures are primarily performed in the absence of another O.R. procedure and generally are not performed with a more intensive

open chest procedure, that we should evaluate cases reporting LAAC procedures with the other approaches in their assigned MS–DRGs.

As indicated in the proposed rule, we then examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting LAAC procedures with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274. Our findings are shown in the following table.

MS-DRGs 273 and 274 - LAAC Procedures with Percutaneous or Percutaneous Endoscopic Approach

MS-DRG	ICD-10-PCS code	Number of Cases	Average Length of Stay	Average Costs
273	All Cases	7,048	6.1	$28,100
	LAAC procedures with percutaneous or percutaneous endoscopic approach	1,180	2.9	$29,591
274	All Cases	24,319	2.0	$24,048
	LAAC procedures with percutaneous or percutaneous endoscopic approach	13,774	1.2	$25,765

In MS–DRG 273, we found a total of 7,048 cases with an average length of stay of 6.1 days and average costs of $28,100. Of those 7,048 cases, there were 1,180 cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach, with an average length of stay of 2.9 days and average costs of $29,591. In MS–DRG 274, we found a total of 24,319 cases with an average length of stay of 2.0 days and average costs of $24,048. Of those 24,319 cases, there were 13,774 cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach, with an average length of stay of 1.2 days and average costs of $25,765.

The analysis shows that the cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274 have very similar average costs compared to all the cases in MS–DRGs 273 and 274 ($29,591 versus $28,100 and $25,765 versus $24,048, respectively). The analysis also shows that the average length of stay for cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274 is shorter compared to all cases in MS–DRGs 273 and 274 (2.9 days versus 6.1 days and 1.2 days versus 2.0 days, respectively). Overall, there were a total of 14,954 (1,180 + 13,774) cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274 with an average length of stay of 1.3 days and average costs of $26,067.

We stated in the proposed rule that our clinical advisors did not support creating a new MS–DRG for all LAAC procedures for FY 2021. Rather, our clinical advisors believe that ICD–10–PCS codes 02L70CK, 02L70DK, and 02L70ZK that describe a LAAC procedure with an open approach are more suitably grouped to MS–DRGs 273 and 274. As indicated in the proposed rule our clinical advisors stated that this reassignment would allow all LAAC procedures to be grouped together under the same MS–DRGs and would improve clinical coherence. We noted that all the procedure codes describing LAAC procedures are designated as non-O.R. procedures that affect the MS–DRG to which they are assigned. Therefore, in the proposed rule, we proposed to reassign ICD–10–PCS codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with and without MCC, respectively) to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively).

Comment: Several commenters supported CMS' proposal to not reassign cases reporting ICD–10–PCS procedure code 02L73DK from MS–DRG 274 to MS–DRG 273 and to not revise the title for MS–DRG 273 to ''Percutaneous Intracardiac Procedures with MCC or Major Device Implant for Left Atrial Appendage Closure Procedures''. A commenter concurred that MS–DRG categories should not be based on a specific medical technology or unique procedure code. The commenter noted that the MS–DRGs are intended to group procedures with both similar resource intensity and clinical characteristics. This commenter further noted that the MS–DRG categories are not intended to benefit a single technology or be narrowly constituted such as by singling out a device implant in a field with multiple other techniques and technologies that address a similar disease that do not require an implant. The commenter stated that if CMS were to change its methodology of comparing the procedure requested for reassignment to all cases, as was requested for the WATCHMAN™ LAAC device, then in fairness, CMS should do so for all the other procedure code MS–DRG reassignment requests it receives and that this kind of methodological change should be outlined in the proposed rule for comments so stakeholders can discuss the implications. This commenter also stated its belief that it is premature to modify the Percutaneous Intracardiac Procedures MS–DRGs at this time, because there are a number of technologies in this field using different techniques, including non-implanted devices, and are being studied in CMS Investigational Device Exemption (IDE) approved clinical trials. According to the commenter, it is anticipated that some of these technologies will receive marketing authorization in the near future and therefore, they should also be considered in any MS–DRGs reclassification. In addition, the commenter stated that volume, costs, and length of stay data for the procedures utilizing these technologies

may not be fully incorporated in current hospital cost data, and current clinical trial pricing for these devices, which is lower than commercialized pricing, will not fully reflect true hospital costs. The commenter noted it is critical to ensure that as these alternative technologies are adopted by hospitals that they are not disadvantaged in their MS–DRG assignments, particularly relative to existing implant technologies. The commenter agreed that MS–DRGs 273 and MS–DRG 274 should continue to be broadly constituted to include the full range of procedures performed within the heart chambers using intracardiac techniques. The commenter also agreed with CMS that the title of MS–DRG 273 should remain ''Percutaneous Intracardiac Procedures'' and not reference device implants or be limited to a particular device approach when numerous other options exist and or are in clinical trials. The commenter stated that to the extent CMS implements MS–DRG changes impacting the assignment for WATCHMAN™ LAAC procedures, they request that such policies apply to all LAA procedures, regardless of specific technique, including whether they involve an implant.

Response: We appreciate the commenters' support of our proposal to maintain cases reporting procedure code 02L73DK in MS–DRG 274 and to retain the current titles for MS–DRGs 273 and 274 by not revising to include terminology referencing an implant. As discussed in the proposed rule, we agree that the MS–DRGs are intended to group procedures with both similar resource intensity and clinical characteristics, rather than to identify a specific, single technology, identified by only one unique procedure code. We further note that we would expect to discuss any changes to CMS' current methodology for evaluating MS–DRG requests involving reassignment of a procedure code in future rulemaking. We appreciate the information provided by the commenter regarding additional technologies and techniques for this clinical area that are under study in CMS Investigational Device Exemption (IDE) approved clinical trials and agree they should also be considered in any potential future MS–DRG reclassification.

Comment: We received a comment (from the requestor) expressing concern that in the proposed rule, CMS' summary of the requestor's analysis for the average costs of LAAC procedures reporting ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach), which identifies the WATCHMAN™ device, may have been misunderstood. The commenter clarified that the $3,405 it referenced in its analysis represented the difference between the average costs of the cases identified by procedure code 02L73DK in MS–DRGs 273 and 274 versus all other procedure codes that do not identify the WATCHMAN™ device in MS–DRGs 273 and 274. The commenter stated its belief that a comparison of the cases reporting procedure code 02L73DK ''WATCHMAN™ cases'' versus ''non-WATCHMAN™'' cases is more appropriate to evaluate cost alignment, opposed to the comparison of procedure code 02L73DK to all cases in MS–DRG 273 and 274. The commenter noted that comparing the cases reporting procedure code 02L73DK (''WATCHMAN™ cases'') against all cases includes cases reporting procedure code 02L73DK (''WATCHMAN™ cases'') and effectively compares ''WATCHMAN cases'' to a pool of procedures in which ''WATCHMAN cases'' are a significant subgroup, and therefore influences the MS–DRGs cost. The commenter stated their belief that an accurate cost comparison requires an evaluation of two distinct groups (that is, WATCHMAN™ procedures vs. non-WATCHMAN™ procedures), as opposed to comparing one group against another of which it is a part (that is, Watchman™ procedures vs. all procedures in the MS–DRG category). The commenter also stated that if CMS intends to use a methodology in which clinical/economic coherence is based upon a comparison against the group in which that procedure is already represented, this should be clarified for consistency in future rulemaking. The commenter provided an updated data analysis using FY 2019 MedPAR and concluded that there is greater cost coherence between WATCHMAN™ cases currently assigned to DRG 274 and Non-WATCHMAN™ cases currently assigned to DRG 273 (a difference of $2,019), as opposed to Non-WATCHMAN™ cases currently assigned to DRG 274 (a difference of $4,059). The commenter reiterated its request for CMS to reassign all cases with procedure code 02L73DK from MS–DRG 274 to MS–DRG 273 and rename MS–DRG 273 ''Percutaneous Intracardiac Procedures with MCC or Major Device Implant for LAAC''.

Response: We thank the commenter for the additional information and analysis provided. In response to the commenter's concern that CMS' summary of the requestor's analysis was misunderstood, we note that we inadvertently omitted the reference to MS–DRG 273 in our statement that read, ''According to the requestor's analysis, the average cost for LAAC procedures reporting ICD–10–PCS procedure code 02L73DK is $3,405 higher than the average cost for all cases in MS–DRG 274.'' For clarification, the statement should have read, ''According to the requestor's analysis, the average cost for LAAC procedures reporting ICD–10–PCS procedure code 02L73DK is $3,405 higher than the average cost for all cases in MS–DRG 273 and 274.'' With regard to the commenter's remarks that an accurate cost comparison requires an evaluation of two distinct groups, as opposed to comparing one group against another of which it is a part, we note that we consider this information and the data in this way to understand the impact of the selected cases, however, we have generally not included this specific information in our discussions or summaries of our analysis. The claims data that is evaluated as part of the overall analysis includes the ''with'' and ''without'' cases related to the specific request where applicable, therefore, CMS can consider including this additional data analysis information in future rulemaking. With respect to the commenter's statement that CMS should clarify in future rulemaking if it intends to use a methodology in which clinical/economic coherence is based upon a comparison against the group in which that procedure is already represented, we note that due to the structure of the MS–DRGs and the CC/MCC subgroups that exist, it is not entirely feasible to expect that a comparison would not include other MS–DRGs in which that procedure is already assigned. For the reasons previously discussed in the FY 2021 IPPS/LTCH PPS proposed rule, our clinical advisors continue to support the current structure of MS–DRGs 273 and 274 where all LAAC procedures, with or without an implant, are grouped together. Therefore, after consideration of the public comments that we received, we are finalizing our proposal to not reassign cases reporting ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) from MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) to MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC).

Comment: Several commenters supported CMS' proposal to reassign ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274.

A commenter stated that reassignment of these procedure codes is more representative of the average costs and average length of stay associated with procedures in the logic for MS–DRGs 273 and 274 compared to the procedures that are included in the logic for MS–DRGs 250 and 251. A commenter also suggested that CMS revise the titles for MS–DRGs 273 and 274 to ''Percutaneous and Other Intracardiac Procedures with and without MCC, respectively'', since the current MS–DRG titles suggest that only percutaneous procedures apply to these MS–DRGs. However, a commenter did not support CMS' proposal to reassign ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274 because according to the commenter, it would result in an inappropriate grouping of open procedures under the title of ''percutaneous'' procedures. The commenter asserted that although open atrial appendage closures are rarely performed as standalone procedures and are normally performed in conjunction with open coronary bypass and open valve procedures, if an open atrial appendage closure is actually performed standalone, MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), would more appropriately compensate for the resources and longer length of stays expected with open heart procedures.

Another commenter stated they understood CMS' rationale for not proposing to create a separate MS–DRG for the insertion of WATCHMAN™ devices since the cost reductions involved in their shorter length of stay balances out the costs of the device.

Response: We appreciate the commenters' support of the proposal to reassign ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274. We also agree with the commenter who suggested that the titles for MS–DRGs 273 and 274 should be revised to ''Percutaneous and Other Intracardiac Procedures with and without MCC, respectively'', to reflect this reassignment, as the current MS–DRG titles refer only to percutaneous procedures. In response to the commenter who did not agree with the proposal to reassign procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274 based on the current titles of the MS–DRGs, as we have done in prior rulemaking and as another commenter suggested, we may revise the title of a MS–DRG to better reflect the procedures assigned to it. With regard to the commenter's statement that open LAAC procedures are normally performed in conjunction with open coronary bypass and open valve procedures, therefore, if an open atrial appendage closure is actually performed standalone, it would more appropriately compensate for the resources and longer length of stays expected with open heart procedures if assigned to MS–DRGs 228 and 229, we consider this comment to be outside the scope of the proposal discussed. We can consider additional claims data analysis for these procedures in future rulemaking. With respect to the commenter who stated they understood CMS' rationale for not proposing to create a separate MS–DRG for the insertion of WATCHMAN™ devices since the cost reductions involved in their shorter length of stay balances out the costs of the device, we are unclear as to what this comment is in reference to as there was no discussion in the FY 2021 IPPS/LTCH PPS proposed rule about proposing to create a separate MS–DRG for procedures involving the insertion of a WATCHMAN™ device, rather the discussion concerned reassigning cases reporting the procedure code describing the insertion of a WATCHMAN™ device.

After consideration of the public comments that we received, we are finalizing our proposal to reassign ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274, and are finalizing a revision to the titles for MS–DRG 273 and 274 to Percutaneous and Other Intracardiac Procedures with and without MCC, respectively to reflect this reassignment for FY 2021.

b. Endovascular Cardiac Valve Replacement and Supplement Procedures

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32495 through 32496), we discussed a request we received to revise MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively) by removing the current two-way severity level split and creating a base MS–DRG without any severity level splits. According to the requestor, patients treated with an endovascular cardiac valve replacement procedure have severe heart failure due to a valvular disorder, which may be documented as either an exacerbation of heart failure or as chronic severe heart failure.

The requestor noted that in the cases reporting an endovascular cardiac valve replacement procedure, a secondary diagnosis code describing the specific type of heart failure may be the only MCC reported on the claim and in instances where the heart failure diagnosis code is reported as the principal diagnosis on a claim, it is disregarded from acting as a MCC. In both scenarios, the requestor reported that the heart failure is treated with the endovascular cardiac valve replacement procedure, fluid balance, and medication.

The requestor also stated that providers are challenged in reaching a consensus regarding this subset of patients' symptoms that may be helpful in establishing a diagnosis for exacerbation of heart failure versus chronic severe heart failure and stated that a single, base MS–DRG would assist in the calculation of costs and charges more reliably, regardless of the diagnosis reported in combination with the endovascular cardiac valve replacement procedure.

We noted in the proposed rule that we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 266 and 267. Our findings are shown in the following table.

MS-DRGs for Endovascular Cardiac Valve Replacement and Supplement Procedures

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 266-All cases	19,012	5.3	$50,879
MS-DRG 267-All cases	27,084	2.1	$40,471

As shown in the table, there was a total of 19,012 cases with an average length of stay of 5.3 days and average costs of $50,879 in MS–DRG 266. For MS–DRG 267, there was a total of 27,084 cases with an average length of stay of 2.1 days and average costs of $40,471.

As indicated in the proposed rule, to evaluate the request to create a single MS–DRG for cases reporting endovascular cardiac valve procedures, we conducted an analysis of base MS–DRG 266. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 266 using the September 2018 update of the FY 2018 MedPAR file and the September 2019 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2021. Our findings are shown in the table.

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases Non CC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs Non CC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	46,096	19,012	21,361	5,723	$44,764	$50,879	$40,589	$40,032	$45,435	$40,471
2018	43,382	18,383	19,924	5,075	$44,593	$50,312	$40,936	$38,234	$45,435	$40,387

As shown in the table, the data reflect that the criteria for a two-way split (''with MCC'' and ''without MCC'') are satisfied using both the data from the September 2018 update of the FY 2018 MedPAR file and the data from the September 2019 update of the FY 2019 MedPAR file: (1) At least 500 cases are in the MCC group and in the without MCC subgroup; (2) at least 5 percent of the cases in the MS–DRG are in the MCC group and in the without MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC group and the without MCC group; (4) at least a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) at least a 3-percent reduction in cost variance, indicating that the current severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the current MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. We stated in the proposed rule that our clinical advisors also did not agree with the requestor's assertion that a single, base MS–DRG would assist in calculating costs more reliably. As shown in the claims data and stated previously, the criteria are satisfied for the current two-way split. We further noted that the basis for the MS–DRGs is to better recognize severity and complexity of services, which is accomplished through the CC subgroups.

Based on the results of our analysis, for FY 2021, we proposed to maintain the current structure of MS–DRGs 266 and 267 with a two-way severity level split and not create a single, base MS–DRG.

Comment: Commenters supported CMS' proposal to retain the structure of MS–DRGs 266 and 267 with the current two-way severity level split based on the information and data analysis provided. A commenter also acknowledged the requestor's sentiments regarding situations where a secondary diagnosis code describing the specific type of heart failure may be the only MCC reported on the claim and in instances where the heart failure diagnosis code is reported as the principal diagnosis on a claim, it is disregarded from acting as a MCC. This commenter stated that inconsistencies in the MS–DRG CC Exclusion List for heart failure also confound the issues involving heart failure. The commenter suggested that CMS consider the following:

- Allow all acute heart failure codes to be sequenced as a principal diagnosis to serve as its own MCC in the same manner that acute cor pulmonale serves as an MCC when sequenced as a principal diagnosis with acute pulmonary embolism.

- Amend the CC Exclusion List as to eliminate list 682 for all the ICD–10–CM codes listed in this section of this rule and place all of them in list 2025. The commenter stated that if CMS chooses not to do this, it recommends that CMS transition the I50.23, I50.33, I50.41 and I50.43 diagnosis codes into the 2025 category so that all acute AND acute on chronic heart failure (I50.21, I50.23, I50.31, I50.33, I50.41, I50.43) codes are treated equally.

I50.21 MCC 2025:29 codes, Acute systolic (congestive) heart failure
I50.22 CC 0682:30 codes, Chronic systolic (congestive) heart failure
I50.23 MCC 0682:30 codes, Acute on chronic systolic (congestive) heart failure
I50.30 CC 0682:30 codes, Unspecified diastolic (congestive) heart failure
I50.31 MCC 2025:29 codes, Acute diastolic (congestive) heart failure
I50.32 CC 0682:30 codes, Chronic diastolic (congestive) heart failure
I50.33 MCC 0682:30 codes, Acute on chronic diastolic (congestive) heart failure
I50.40 CC 0682:30 codes, Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41 MCC 0682:30 codes, Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42 CC 0682:30 codes, Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43 MCC 0682:30 codes, Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure

The commenter also suggested that CMS, as a member of the ICD–10 Coordination and Maintenance Committee, advocate to expand ICD–10–CM diagnosis code I50.9 Heart failure, unspecified, and assign CC and MCC status to these suggested expanded codes, consistent with how the I50.2-, I50.3- and I50.4- series are assigned.

I50.90—Heart failure, unspecified
I50.91—Acute heart failure—should serve as an MCC
I50.92—Chronic heart failure—should serve as a CC
I50.93—Acute on chronic heart failure—should serve as an MCC

According to the commenter, this action would sufficiently eliminate the administrative burden to providers regarding querying the physician for the specific type of heart failure.

Response: We appreciate the commenters' support. In response to the commenter who suggested modifying the logic of all the acute heart failure codes to allow them to act as their own MCC or to amend the CC Exclusion list, we appreciate the commenter's suggestions. However, because we consider these public comments to be

outside the scope of the proposed rule, we are not addressing them in this final rule. With regard to the commenter's suggestion to expand diagnosis code I50.9 Heart failure, unspecified, as discussed in section II.E.16. of the preamble of this final rule, the CDC/NCHS has lead responsibility for the diagnosis code classification and proposals for code updates should be directed to *nchsicd10CM@cdc.gov* for consideration at a future ICD–10 Coordination and Maintenance Committee meeting. In addition, as discussed in section II.E.1.b. of the preamble of this final rule, we are maintaining the November 1 deadline for the submission of MS–DRG classification requests for FY 2022, therefore, with regard to the additional suggestions to modify the logic of all the acute heart failure codes to allow them to act as their own MCC or amend the CC Exclusion list, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than November 1, 2020 so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

After consideration of the public comments that we received, we are finalizing our proposal to maintain the structure of MS–DRGs 266 and 277 for FY 2021.

c. Insertion of Cardiac Contractility Modulation Device

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32496), we received a request to review the MS–DRG assignment for cases that identify patients who receive a cardiac contractility modulation (CCM) device system for congestive heart failure. CCM is indicated for patients with moderate to severe heart failure resulting from either ischemic or non-ischemic cardiomyopathy. CCM utilizes electrical signals which are intended to enhance the strength of the heart and overall cardiac performance. CCM delivery device systems consist of a programmable implantable pulse generator (IPG) and three leads which are implanted in the heart. One lead is implanted into the right atrium and the other two leads are inserted into the right ventricle. The lead in the right atrium detects atrial electric signals and transmits them to the IPG. The IPG, which is usually implanted into the subcutaneous pocket of the pectoral region and secured to the fascia with a non-absorbable suture, processes the atrial signal and generates the CCM signals which are transmitted to the right ventricle via the two ventricular leads. According to the requestor, MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively) include code combinations or ''code pairs'' describing the insertion of contractility modulation devices. Currently however, the MS–DRG GROUPER logic requires the combination of the CCM device codes and a left ventricular lead to map to MS–DRGs 222, 223, 224, 225, 226 and 227. The requestor stated the CCM device is contraindicated in patients with a left ventricular lead. Therefore, using the current V37 MS–DRG GROUPER logic, no case involving insertion of the CCM system can be appropriately mapped to MS–DRGs 222, 223, 224, 225, 226 and 227. Instead, the cases map to MS–DRG 245 (AICD Generator Procedures). According to the requestor, to date, the procedure has been performed on an outpatient basis, but it is expected that some Medicare patients will receive CCM devices on an inpatient basis. The requestor asked that CMS revise the MS–DRG GROUPER logic to group cases reporting the use of the CCM device appropriately.

As noted in the proposed rule, the ICD–10–PCS procedure code pairs currently assigned to MS–DRGs 222, 223, 224, 225, 226 and 227 that identify the insertion of contractility modulation devices are shown in the following table:

ICD-10-PCS Code	Code Description
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous
0JH83AZ	approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous
0JH83AZ	approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous
0JH83AZ	approach

We stated in the proposed rule that based on our analysis of cases reporting ICD–10–PCS procedure codes for CCM device systems, we agreed with the requestor that a procedure code pair for the insertion of a CCM device and right ventricular and/or right atrial lead does not exist in the logic for MS–DRGs 222, 223, 224, 225, 226 and 227. We also noted that our analysis indicated that the ICD–10–PCS procedure code combinations for right ventricular and/or right atrial lead insertion with insertion of contractility modulation devices were inadvertently excluded from MS–DRGs 222, 223, 224, 225, 226 and 227 as a result of replicating the ICD–9 based MS–DRGs.

We then examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRG 245 and identified the subset of cases within MS–DRG 245 reporting procedure codes for the insertion of a rechargeable CCM device and the insertion of right ventricular and/or right atrium lead. We found zero cases in MS–DRG 245 reporting a procedure code combination that identifies the insertion of contractility modulation device and the insertion of a cardiac lead into the right ventricle and/or right atrium lead.

We stated that our clinical advisors agreed that the insertion of a rechargeable CCM system always involves placement of a right-sided lead, and that the code combinations that currently exist in the MS–DRG GROUPER logic are considered clinically invalid. We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 222, 223, 224, 225, 226 and 227 for this subset of cases to determine if there were any cases that reported one of the 12 clinically invalid code combinations that exist in the GROUPER logic. Because the combinations of codes that describe the insertion of a rechargeable CCM device and the insertion of left ventricular lead are considered clinically invalid procedures, we stated we would not expect these code combinations to be reported in any claims data. We found zero cases across MS–DRGs 222, 223, 224, 225, 226 and 227 reporting the clinically invalid procedure code combination that identifies the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle.

We noted that while our analysis did not identify any cases reporting a procedure code combination for the insertion of contractility modulation device and the insertion of a cardiac lead into right ventricle or right atrium, recognizing that it is expected that some Medicare patients will receive CCM devices on an inpatient basis, we proposed to add the following 24 ICD–10–PCS code combinations to MS–DRGs 222, 223, 224, 225, 226 and 227.

We also proposed to delete the 12 clinically invalid code combinations from the GROUPER logic of MS–DRGs 222, 223, 224, 225, 226 and 227 that describe the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle.

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ICD-10-PCS Code	Code Description
02HK0MZ with 0JH60AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HK3MZ with 0JH60AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HK4MZ with 0JH60AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HK0MZ with 0JH63AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HK3MZ with 0JH63AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HK4MZ with 0JH63AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HK0MZ with 0JH80AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HK3MZ with 0JH80AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HK4MZ with 0JH80AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HK0MZ with 0JH83AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02HK3MZ with 0JH83AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02HK4MZ with 0JH83AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02H60MZ with 0JH60AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach

ICD-10-PCS Code	Code Description
02H63MZ with 0JH60AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02H64MZ with 0JH60AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02H60MZ with 0JH63AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02H63MZ with 0JH63AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02H64MZ with 0JH63AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02H60MZ with 0JH80AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02H63MZ with 0JH80AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02H64MZ with 0JH80AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02H60MZ with 0JH83AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02H63MZ with 0JH83AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02H64MZ with 0JH83AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach

BILLING CODE 4120–01–C

Comments: Commenters supported the proposal to modify the GROUPER logic of MS–DRGs 222, 223, 224, 225, 226 and 227 by (1) adding the 24 ICD–10–PCS code combinations describing the insertion of contractility modulation device and the insertion of a cardiac lead into right ventricle or right atrium to MS–DRGs 222, 223, 224, 225, 226 and 227; and (2) deleting the 12 clinically invalid procedure code combinations that describe the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle. A commenter specifically thanked CMS for consulting with their clinical advisors, conducting a thorough analysis regarding these codes, and for determining the most appropriate MS–DRG assignments for cardiac contractility modulation devices. While indicating its support, one commenter questioned why cardiac contractility modulation devices qualify for MS–DRGs 222, 223, 224, 225, 226 and 227 and cardiac resynchronization therapy pacemakers (CRT–P) without defibrillators do not and requested that this be investigated in future rulemaking. This commenter also

suggested that CMS change the name of MS- DRGs 222, 223, 224, 225, 226 and 227 since a cardiac modulation device is not used in all circumstances. Another commenter noted its intention to monitor the deletion of the 12 clinically invalid code combinations from the GROUPER logic in hopes that no unintended consequences come from this change.

Response: We appreciate the commenters' feedback and support.

In response to the commenter that questioned why cardiac contractility modulation devices qualify for MS–DRGs 222, 223, 224, 225, 226 and 227 and cardiac resynchronization therapy pacemakers do not, procedures involving CRT–P are assigned to a number of MS–DRGs. Specifically, in MDC 05 (Diseases and Disorders of the Circulatory System), procedures involving these pacemakers are assigned to MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with MCC and without MCC, respectively), and MS–DRGs 260, 261 and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively).

Procedures codes describing the insertion of total contractility modulation device systems have been assigned to MS–DRGs 222, 223, 224, 225, 226 and 227 since the initial implementation of these procedure codes in FY 2010 under ICD–9–CM, recognizing that insertion of the CCM device might occur alone, in the presence of a pre-existing automatic implantable cardioverter-defibrillator (AICD), or in a combined implantation with an AICD. As stated in the proposed rule, the ICD–10–PCS procedure code combinations for right ventricular and/or right atrial lead insertion with insertion of contractility modulation devices were inadvertently excluded from MS–DRGs 222, 223, 224, 225, 226 and 227 as a result of replicating the ICD–9 based MS–DRGs. Recognizing that clinical practice might have changed since the creation of codes for CCM devices, our clinical advisors believe additional analyses are needed in MDC 05, specifically for cases reporting both contractility modulation device systems and pacemakers, as part of our efforts toward a broader approach to refining MS–DRGs and to address the commenters' request. As such, we also do not believe conforming changes to the titles of MS–DRGs 222, 223, 224, 225, 226 and 227 are warranted at this time until further review is complete.

CMS also will monitor claims data for unintended consequences as a result of the deletion of the 12 clinically invalid code combinations from the GROUPER logic as we continue our comprehensive analysis in future rulemaking. Therefore, after consideration of the public comments we received, we are finalizing our proposal to add the 24 ICD–10–PCS code combinations as previously listed to MS–DRGs 222, 223, 224, 225, 226 and 227. We are also finalizing our proposal to delete the 12 clinically invalid code combinations from the GROUPER logic of MS–DRGs 222, 223, 224, 225, 226 and 227 that describe the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle under the ICD–10 MS–DRGs Version 38, effective October 1, 2020.

6. MDC 6 (Diseases and Disorders of the Digestive System): Acute Appendicitis

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32500 through 32503), we discussed a request that we received to add ICD–10–CM diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) to the list of complicated principal diagnoses that group to MS–DRGs 338, 339 and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) so that all ruptured/perforated appendicitis codes in MDC 06 (Diseases and Disorders of the Digestive System) group to MS–DRGs 338, 339, and 340. ICD–10–CM diagnosis code K35.20 currently groups to MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Under current coding conventions, the following inclusion term for subcategory K35.2 (Acute appendicitis with generalized peritonitis) is: Appendicitis (acute) with generalized (diffuse) peritonitis following rupture or perforation of the appendix. The requestor also noted that diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) currently groups to MS–DRGs 338, 339, and 340, however, diagnosis code K35.20 which describes a generalized, more extensive form of peritonitis does not. The requestor stated that ICD–10–CM diagnosis code K35.20 is the only ruptured appendicitis code not included in the list of complicated principal diagnosis codes for MS–DRGs 338, 339 and 340 and stated that it is clinically appropriate for all ruptured/perforated appendicitis diagnosis codes to group to MS–DRGs 338, 339 and 340.

As indicated in the FY 2021 IPPS/LTCH PPS proposed rule, we analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases in MS–DRGs 341, 342, and 343 and claims reporting ICD–10–CM diagnosis code K35.20 as a principal diagnosis. Our findings are shown in the following table.

MS-DRG	ICD-10-CM Code	Number of Cases	Average Length of Stay	Average Costs
341	All cases	718	5.9	$17,270
	K35.20	62	7.8	$20,244
342	All cases	2,184	3.4	$10,611
	K35.20	183	4.2	$10,952
343	All cases	2,329	2.0	$8,298
	K35.20	137	2.6	$8,088

As shown in the table, we found a total of 718 cases with an average length of stay of 5.9 days and average costs of $17,270 in MS–DRG 341. Of those 718 cases, there were 62 cases reporting a principal diagnosis code of K35.20 with

an average length of stay of 7.8 days, and average costs of $20,244. We found a total of 2,184 cases with an average length of stay of 3.4 days and average costs of $10,611 in MS–DRG 342. Of those 2,184 cases there were 183 cases reporting a principal diagnosis code of K35.20 with an average length of stay of 4.2 days, and average costs of $10,952. We found a total of 2,329 cases with an average length of stay of 2.0 days and average costs of $8,298 in MS–DRG 343. Of those 2,329 cases, there were 137 cases reporting a principal diagnosis code of K35.20 with an average length of stay of 2.6 days, and average costs of $8,088.

As indicated in the proposed rule, we also analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 338, 339, and 340. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
338	685	8.1	$20,930
339	2,245	5.0	$12,705
340	1,840	2.9	$9,101

As shown in the table, we found a total of 685 cases with an average length of stay of 8.1 days and average costs of $20,930 in MS–DRG 338. We found a total of 2,245 cases with an average length of stay of 5.0 days and average costs of $12,705 in MS–DRG 339. We found a total of 1,840 cases, average length of stay 2.9 days, and average costs of $9,101 in MS–DRG 340.

We stated in the proposed rule that our clinical advisors agreed that the presence of an abscess would clinically determine whether a diagnosis of acute appendicitis would be considered a complicated principal diagnosis. As diagnosis code K35.20 is described as ''without'' an abscess, we stated our clinical advisors recommended that it not be added to the list of principal diagnoses for MS–DRGS 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). We stated in the proposed rule, that we believe that while the average costs for cases reporting diagnosis code K35.20 are similar to the cases in MS–DRGs 338, 339, and 340, diagnosis codes describing acute appendicitis that do not indicate the presence of an abscess should remain in MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Therefore, we did not propose to reassign diagnosis code K35.20 from MS–DRGs 341, 342, and 343 to MS–DRGs 338, 339, and 340.

As noted previously, the requestor pointed out that diagnosis K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) currently groups to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Therefore, in the proposed rule, we identified all the diagnosis codes describing acute appendicitis within the ICD–10–CM classification under subcategory K35.2 (Acute appendicitis with generalized peritonitis) and subcategory K35.3 (Acute appendicitis with localized peritonitis) and reviewed their respective MS–DRG assignments for clinical coherence. The diagnosis codes in these subcategories are shown in the following table.

ICD-10-CM Code	Description
K35.20	Acute appendicitis with generalized peritonitis, without abscess
K35.21	Acute appendicitis with generalized peritonitis, with abscess
K35.30	Acute appendicitis with localized peritonitis, without perforation or gangrene
K35.31	Acute appendicitis with localized peritonitis and gangrene, without perforation
K35.32	Acute appendicitis with perforation and localized peritonitis, without abscess
K35.33	Acute appendicitis with perforation and localized peritonitis, with abscess

As indicated in the proposed rule, we analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting any one of the ICD–10–CM diagnosis codes as previously listed as a principal diagnosis in MS–DRGs 338, 339, 340, 341, 342, and 343. Our findings are shown in the following table.

ICD-10-CM Code	MS-DRG	Number of Cases	Average Length of Stay	Average Costs
K35.20	341	62	7.8	$20,244
	342	183	4.1	$10,952
	343	137	2.6	$8,088
K35.21	338	33	11.2	$26,267
	339	94	6.8	$15,490
	340	44	3.6	$9,364
K35.30	341	65	4.5	$13,458
	342	278	3.0	$9,176
	343	288	1.8	$7,250
K35.31	341	20	6.2	$15,826
	342	90	3.9	$10,176
	343	90	2.4	$7,664
K35.32	338	329	7.7	$19,775
	339	1221	4.5	$11,870
	340	1067	2.7	$8,903
K35.33	338	285	8.5	$22,342
	339	894	5.6	$13,523
	340	718	3.1	$9,373

As shown in the table, the diagnosis codes describing ''with abscess'' (K35.21 and K35.33) are currently assigned to MS–DRGs 338, 339, and 340. In addition, the diagnosis codes describing ''without abscess'' (K35.20, K35.30, and K35.31) are currently assigned to MS–DRGs 341, 342, and 343. We stated in the proposed rule, that our clinical advisors believe that cases reporting ICD–10–CM diagnosis codes describing ''with abscess'' are associated with higher severity of illness and resource consumption because of extended lengths of stay and treatment with intravenous antibiotics. Therefore, in the proposed rule, we noted that our clinical advisors determined that diagnosis code K35.32 should also be assigned to MS–DRGs 341, 342, and 343 for clinical consistency.

Accordingly, in the proposed rule, we proposed to reassign diagnosis code K35.32 to MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

As also noted in the proposed rule, the ICD–10 MS–DRG Version 37 Definitions Manual currently lists the following ICD–10–CM diagnosis codes as Complicated Principal Diagnoses in MS–DRGs 338, 339, 340, 341, 342, and 343: C18.1 (Malignant neoplasm of appendix); C7A.020 (Malignant carcinoid tumor of the appendix); K35.21 (Acute appendicitis with generalized peritonitis, with abscess); K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) and K35.33 (Acute appendicitis with perforation and localized peritonitis, with abscess). For the same reasons discussed previously, we proposed to remove diagnosis code K35.32 from the complicated principal diagnosis list to be clinically consistent.

Therefore, for the reasons discussed, in the proposed rule, we proposed to (1) maintain the current assignment of diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) in MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); (2) reassign diagnosis code K35.32 from MS–DRGs 338, 339 and 340 to MS–DRGs 341, 342, and 343; and (3) remove diagnosis code K35.32 from the complicated principal diagnosis list in MS–DRGs 338, 339, and 340 as listed in the ICD–10 MS–DRG Version 37 Definitions Manual.

Comment: Commenters' supported CMS' proposal to reassign diagnosis code K35.32 from MS–DRGs 338, 339 and 340 to MS–DRGs 341, 342, and 343 and to remove K35.32 from the complicated principal diagnosis list in MS–DRGs 338, 339, and 340. One commenter stated that the ''peritonitis'' described by the diagnoses code may be just reactive peritonitis from the appendicitis and therefore would not be associated with an abscess or an increased length of stay. Another commenter supported CMS' proposal not to reassign ICD–10–CM diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) from MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). The commenter stated their agreement with CMS clinical advisors that the presence of an abscess should clinically determine whether a diagnosis of acute appendicitis would be considered a complicated principal diagnosis, therefore all diagnosis codes for acute appendicitis ''without'' abscess should be assigned to MS–DRGs 341, 342, and 343 for clinical consistency.

Response: We appreciate the commenters' support.

Comment: One commenter stated that they disagreed with CMS on clinical grounds that ICD–10–CM code K35.20 is not a complicating diagnosis, and that all ICD–10–CM codes in subcategory K35.2 (Acute appendicitis with

generalized peritonitis) should serve as an MCC in the same manner that unspecified peritonitis serves as an MCC. This commenter also stated that given that acute appendicitis is more commonly encountered in non-Medicare patients and that MS–DRGs are a common payment methodology for private insurance and Medicaid claims, CMS should additionally analyze Medicaid claims.

Response: We thank the commenter for their feedback. We note diagnosis codes for acute appendicitis described as ''without abscess'' or ''without perforation'' were assigned the CC severity level designation in FY 2019 when diagnosis code K35.2 was subdivided into diagnosis codes K35.20 (Acute appendicitis with generalized peritonitis, without abscess) and K35.21 (Acute appendicitis with generalized peritonitis, with abscess) because our clinical advisors stated cases ''without abscess'' or ''without perforation'' are not as severe clinical conditions compared to cases ''with abscess'' or ''with perforation'' as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41230). However, as noted in section II.E.12.b. of the preamble of this final rule, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We continue to solicit comments regarding these guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We encourage the commenter to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for diagnosis code K35.20. Commenters should submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2020.

Comment: Some commenters opposed CMS' proposal to maintain the current MS–DRG assignment for ICD–10–CM diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess). A commenter stated that the costs for treating acute appendicitis with generalized peritonitis are on the higher end of the scale as CMS's data demonstrated in the proposed rule and requested that CMS reconsider the request to move principal diagnosis code K35.20 from MS–DRGs 341, 342, and 343 to MS–DRGs 338, 339 and 340 based on the severity of illness and the cost of treatment. The commenter stated that when ruptured appendicitis results in generalized peritonitis, resources are greater because the infection is not walled off, not localized, and has spread to two or more compartments within the abdominal cavity. According to the commenter, clinical literature supports the statement that generalized peritonitis is a more morbid (severe) presentation than just perforation or localized abscess. The commenter also stated that close postoperative monitoring is required to identify any signs of sepsis or organ dysfunction indicating persistent abdominal infection requiring intra-abdominal lavage via postoperative drains or relaparotomy. In addition, according to the commenter, antibiotics are given to the patient for 5–7 days until temperature and white blood cell count are within normal limits. Another commenter stated that the condition described by diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) can be associated with a risk of post-operative abscess formation and extended length of hospital stay, thereby warranting the classification as a complicated diagnosis. The commenter urged CMS to reassign diagnosis code K35.20 from MS–DRGs 341, 342, and 343 to MS–DRGs 338, 339 and 340. Another commenter stated that diagnosis code K35.20, is a complicated diagnosis on clinical grounds and strongly believes that when sequenced as a principal diagnosis along with an appendectomy should continue to group to MS–DRGs 338, 339 and 340.

Other commenters did not support the proposal to reassign diagnosis code K35.32 from MS–DRGs 338, 339 and 340 to MS–DRGs 341, 342, and 343 and urged CMS to reconsider reassigning diagnosis code K35.32. A commenter stated that the condition described by ICD–10–CM diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) represents a complicated diagnosis, and asked CMS to maintain the current complicated diagnosis classification for code K35.32. Another commenter analyzed data from their facility and found claims reporting a principal diagnosis of K35.32 in MS–DRGs 338, 339 and 340 had an average LOS of 4.18 days and average charges of $60,000. This commenter stated when compared to claims at their facility grouped to MS–DRGs 341, 342 and 343, which had an average length of stay of 1.91 days and average charges of $42,000, claims reporting principal diagnosis ICD–10–CM diagnosis code K35.32 were more congruent with MS–DRG's 338–340. This commenter also stated it was the professional opinion of the critical care surgical staff of the facility that the presence of appendiceal perforations resulting in peritonitis (with or without abscess) requires longer hospitalizations and increased resources, such as peritoneal washings, intravenous antibiotics, and intravenous hydration to care for the increased severity of illness.

Response: We appreciate the commenters' feedback.

While our clinical advisors continue to believe that when peritonitis develops in a patient with acute appendicitis, the degree and severity of the peritonitis can vary greatly, we concur that the expansion of diagnosis codes K35.2 and K35.3 to introduce additional clinical concepts effective October 1, 2018 significantly changed the scope and complexity of the diagnosis codes for this subset of patients. As noted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41236), when we consulted with the staff at the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS), because NCHS has the lead responsibility for maintaining the ICD–10–CM diagnosis codes, the NCHS' staff acknowledged the clinical concerns based on the manner in which diagnosis codes K35.2 and K35.3 were expanded and confirmed that they would consider further review of these newly expanded codes with respect to the clinical concepts. As such, we believe it would be appropriate to maintain the current assignments at this time in order to further examine the relevant clinical factors and similarities in resource consumption in order to best represent this subset of patients within the MS–DRG classification. Therefore, after consideration of the public comments we received, and for the reasons discussed, diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) will be maintained in MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2021. We are not finalizing our proposal to reassign diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) to MS–DRGs 341, 342, and 343; and we are not finalizing our proposal to remove diagnosis code K35.32 from the complicated principal diagnosis list in MS–DRGs 338, 339, and 340. Accordingly, the assignment of ICD–10–CM code K35.32 will be maintained in MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and

ICD–10–CM diagnosis code K35.32 will continue to be listed as a Complicated Principal Diagnosis in MS–DRGs 338, 339, and 340, in the ICD–10 MS–DRG Version 38 Definitions Manual. As additional claims data become available, we will continue to analyze the clinical nature of each of the diagnoses and their MS–DRG assignments to further improve the overall accuracy of the IPPS payments in future rulemaking.

7. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Cervical Radiculopathy

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32503 through 32505), we received a request to reassign ICD–10–CM diagnosis codes M54.11 (Radiculopathy, occipito-atlanto-axial region), M54.12 (Radiculopathy, cervical region) and M54.13 (Radiculopathy, cervicothoracic region) from MDC 01 (Diseases and Disorders of the Nervous System) to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). The requestor stated that when one of these diagnosis codes describing radiculopathy in the cervical/cervicothoracic area of the spine is reported as a principal diagnosis in combination with a cervical spinal fusion procedure code, the case currently groups to MDC 01 in MS–DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC). The requestor acknowledged that radiculopathy results from nerve impingement, however, the requestor noted it typically also results from a musculoskeletal spinal disorder such as spondylosis or stenosis. According to the requestor, the underlying musculoskeletal cause should be reported as the principal diagnosis if documented. The requestor stated that when the medical record documentation to support a musculoskeletal cause is not available, cases reporting a cervical spinal fusion procedure with a principal diagnosis of cervical radiculopathy would be more consistent with other cervical spinal fusion procedures if they grouped to MDC 08 in MS–DRGs 471, 472, and 473 (Cervical Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). The requestor stated that the following diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine are currently assigned to MDC 08 and therefore, group appropriately to the spinal fusion MS–DRGs in MDC 08.

ICD-10-CM Code	Description
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region

We noted that the requestor is correct that when diagnosis codes M54.11, M54.12 or M54.13 are reported as a principal diagnosis in combination with a cervical spinal fusion procedure, the case currently groups to MDC 01 in MS–DRG 028, MS–DRG 029, and MS–DRG 030. This grouping occurs because the diagnosis codes describing radiculopathy in the cervical/cervicothoracic area of the spine are assigned to MDC 01 and the procedure codes describing a cervical spinal fusion procedure are assigned to MDC 01 in MS–DRGs 028, 029 and 030. We further noted that the requestor is also correct that diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine (M54.14, M54.15, M54.16 and M54.17) are currently assigned to MDC 08 and therefore, group to the spinal fusion MS–DRGs in MDC 08 consistent with the GROUPER logic definitions. The MS–DRGs that involve spinal fusion procedures of the cervical or lumbar regions that are currently assigned in MDC 01 and MDC 08 are listed in the following table.

MDC	MS-DRG	Description
01	028	Spinal Procedures with MCC
	029	Spinal Procedures with CC or Spinal Neurostimulators
	030	Spinal Procedures without CC/MCC
08	453	Combined Anterior/Posterior Spinal Fusion with MCC
	454	Combined Anterior/Posterior Spinal Fusion with CC
	455	Combined Anterior/Posterior Spinal Fusion without CC/MCC
	456	Spinal Fusion Except Cervical with Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions with MCC
	457	Spinal Fusion Except Cervical with Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions with CC
	458	Spinal Fusion Except Cervical with Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions without CC/MCC
	459	Spinal Fusion Except Cervical with MCC
	460	Spinal Fusion Except Cervical without MCC
	471	Cervical Spinal Fusion with MCC
	472	Cervical Spinal Fusion with CC
	473	Cervical Spinal Fusion without CC/MCC

We referred the reader to the ICD–10 MS–DRG Version 37 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the listed MS–DRGs.

As indicated in the FY 2021 IPPS/LTCH PPS proposed rule, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRGs 028, 029, and 030 and for cases reporting any one of the diagnosis codes describing radiculopathy of the cervical/cervicothoracic area of the spine (M54.11, M54.12, or M54.13) in combination with a cervical spinal fusion procedure. We refer the reader to Table 6P.1b associated with the proposed rule and this final rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/* for the list of procedure codes describing a cervical spinal fusion procedure. Our findings are shown in the following table.

Cervical Radiculopathy with Cervical Spinal Fusion Procedures				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
MS-DRG 028	All cases	2,105	11.9	$40,886
	Cases with principal diagnosis of cervical radiculopathy with cervical spinal fusion	22	8.2	$44,980
MS-DRG 029	All cases	3,574	6	$24,026
	Cases with principal diagnosis of cervical radiculopathy with cervical spinal fusion	176	2.6	$24,852
MS-DRG 030	All cases	1,338	3.1	$17,393
	Cases with principal diagnosis of cervical radiculopathy with cervical spinal fusion	166	1.7	$23,003

As shown in the table, there were a total of 2,105 cases with an average length of stay of 11.9 days and average costs of $40,866 in MS–DRG 028. Of those 2,105 cases, there were 22 cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure with an average length of stay of 8.2 days and average costs of $44,980. For MS–DRG 029, there were a total of 3,574 cases with an average length of stay of 6 days and

average costs of $24,026. Of those 3,574 cases, there were 176 cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure with an average length of stay of 2.6 days and average costs of $24,852. For MS–DRG 030, there were a total of 1,338 cases with an average length of stay of 3.1 days and average costs of $17,393. Of those 1,338 cases, there were 166 cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure with an average length of stay of 1.7 days and average costs of $23,003.

We also reviewed the claims data for MS–DRGs 471, 472, and 473. Our findings are shown in the following table.

MS-DRGs for Cervical Spinal Fusion Procedures			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 471- All cases	3,327	9	$36,941
MS-DRG 472- All cases	15,298	3.3	$22,539
MS-DRG 473- All cases	11,144	2	$18,748

As shown in the table, there were a total of 3,327 cases with an average length of stay of 9 days and average costs of $36,941 in MS–DRG 471. There were a total of 15,298 cases with an average length of stay of 3.3 days and average costs of $22,539 in MS–DRG 472. There were a total of 11,144 cases with an average length of stay of 2 days and average costs of $18,748 in MS–DRG 473.

Based on the claims data, the average costs of the cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure are consistent with the average costs of all the cases in MS–DRGs 028, 029, and 030 in MDC 01. We also noted that the average costs of all the cases in MS–DRGs 028, 029, and 030 in MDC 01 are also comparable to the average costs of all the cases in MS–DRGs 471, 472, and 473, respectively; ($40,886 versus $36,941; $24,026 versus $22,539; and $17,393 versus $18,748).

We stated that our clinical advisors do not support reassigning diagnosis codes M54.11, M54.12, and M54.13 that describe radiculopathy in the cervical/cervicothoracic area of the spine from MDC 01 to MDC 08 until further analysis of the appropriate assignment of these and other diagnosis codes describing radiculopathy. As the requestor pointed out, the diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine (M54.14, M54.15, M54.16 and M54.17) are currently assigned to MDC 08. We noted that there are also two other codes to identify radiculopathy within the classification, diagnosis code M54.10 (Radiculopathy, site unspecified) and M54.18 (Radiculopathy, sacral and sacrococcygeal region), both of which are currently assigned to MDC 01. We stated that our clinical advisors recommended maintaining the current assignment of diagnosis codes describing cervical radiculopathy in MDC 01 until further analysis of whether all the diagnosis codes describing radiculopathy of a specified or unspecified site should be assigned to the same MDC and if so, whether those codes should be assigned to MDC 01 or MDC 08. As part of this analysis, they also recommended soliciting further input from the public on the appropriate assignment for all of the diagnosis codes describing radiculopathy, including from professional societies and national associations for neurology and orthopedics. For these reasons, we did not propose to reassign diagnosis codes M54.11, M54.12, and M54.13 from MDC 01 to MDC 08 at this time.

Comment: Commenters agreed with the proposal to maintain the current assignment of diagnosis codes describing cervical radiculopathy in MDC 01 until further analysis of whether all the diagnosis codes describing radiculopathy of a specified or unspecified site should be assigned to the same MDC, and if so, whether those codes should be assigned to MDC 1 or MDC 8. Commenters also agreed with CMS' plan to solicit clinical input from medical specialty societies on the appropriate MDC classification for the diagnosis codes describing radiculopathy. A commenter thanked CMS for the consideration of the request and the solicitation for outside support from the industry while continuing to evaluate. Another commenter recommended reclassifying all cervical spinal fusion procedures to the same MS–DRGs, regardless of the diagnosis for which the procedure is performed. The commenter stated that the main driver for resource utilization is the surgical procedure and the ICD–10–CM diagnosis codes describing radiculopathy of the cervical/cervicothoracic spine would need to be classified to MDC 08 in order to group clinically similar cases under MS–DRGs 471, 472, and 473.

Response: We appreciate the commenters' support. In response to the commenter who recommended reclassifying all cervical spinal fusion procedures to the same MS–DRGs, regardless of the diagnosis for which the procedure is performed, as noted above and stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32505), our clinical advisors recommended maintaining the current assignment of diagnosis codes describing cervical radiculopathy in MDC 01 until further analysis of whether all the diagnosis codes describing radiculopathy of a specified or unspecified site should be assigned to the same MDC as well as further input from the public, including professional societies, and national associations for neurology and orthopedics. We agree with the commenter that the main driver for resource utilization is the surgical procedure and the ICD–10–CM diagnosis codes describing radiculopathy of the cervical/cervicothoracic spine would need to be classified to MDC 08 in order to group clinically similar cases under MS–DRGs 471, 472, and 473, however, it is the diagnosis codes and the MDC to which they should be clinically classified that requires further evaluation. From a clinical perspective, cervical radiculopathy involves inflammation or damage to the nerve root in the cervical spine which can affect a patient's neurological function. The underlying causes and risk factors vary, and depending on the patient's age, may more likely be attributed to a

musculoskeletal condition, an infection, congenital anomaly, injury or a tumor.

After consideration of the public comments that we received, we are maintaining the current assignment of diagnosis codes M54.11, M54.12, and M54.13 describing cervical radiculopathy in MDC 01 for FY 2021, and as discussed intend to further review and analyze all the diagnosis codes describing radiculopathy of a specified or unspecified site to determine if they should be assigned to the same MDC, and if so, whether those codes should be assigned to MDC 1 or MDC 8.

b. Hip and Knee Joint Replacements

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32505 through 32510), we discussed a request we received to restructure the MS–DRGs for total joint arthroplasty that utilize an oxidized zirconium bearing surface implant in total hip replacement and total knee replacement procedures. According to the requestor, several international joint replacement registries, retrospective claims review, and published clinical studies show compelling short-term, mid-term and long-term clinical outcomes for patients receiving these implants. The requestor stated that without specific MS–DRGs, beneficiary access to these implants is restricted and the benefit to patients and cost savings cannot be recognized.

The requestor noted that effective October 1, 2017, new ICD–10–PCS procedure codes describing hip and knee replacement procedures with an oxidized zirconium bearing surface implant were established, which allow greater specificity and provide the ability to track costs and clinical outcomes for the patients who receive the implant. The requestor provided 3 options for CMS to consider as part of its request which are summarized in this section of this rule.

The first option provided by the requestor was to create a new MS–DRG by reassigning cases reporting a hip or knee replacement procedure with an oxidized zirconium bearing surface implant from MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) to the suggested new MS–DRG. The requestor conducted its own analysis and noted that there were approximately 18,000 cases reporting a hip or knee replacement with an oxidized zirconium bearing surface implant and the average length of stay for these cases was shorter in comparison to the cases reporting hip and knee replacement procedures without an oxidized zirconium bearing surface implant. The requestor suggested that patients receiving an oxidized zirconium bearing surface implant may be walking earlier after surgery and the risk of infection may be reduced as a result of the shorter hospitalization.

The requestor stated that separating out these cases reporting the use of an oxidized zirconium bearing surface implant is clinically justified because the implants are designed for increased longevity. The requestor also stated that oxidized zirconium is an entirely distinct material from traditional ceramic or metal implants, as it is made through a unique thermal oxidation process which creates a ceramicised surface while maintaining the biocompatible zirconium alloy substrate. According to the requestor, this process creates an implant with the unique properties of both metals and ceramics: Durability, strength and friction resistance. Conversely, the requestor stated that cobalt chrome used in metal implants contains up to 143x more nickel (<0.5% vs <0.0035%) than oxidized zirconium and that nickel is the leading cause of negative reactions in patients with metal sensitivities.

The requestor asserted that creating a new MS–DRG for hip and knee replacement procedures with an oxidized zirconium bearing surface implant would be a logical extension of the unique procedure codes that CMS finalized and stated that other countries have established higher government reimbursement for these implants to reflect the increased value of the technology. The requestor also asserted that multiple joint replacement registries have reported excellent hip replacement results, including a statistically significant 33 percent reduced risk of revision ($p<0.001$) for oxidized zirconium on highly cross-linked polyethylene (XLPE), from three months compared to the most common bearing surface of metal/XLPE.

Lastly, the requestor stated that multiple U.S. data sources, including Medicare claims, show strong short-term outcomes, reduced 30-day readmissions, fewer discharges to skilled nursing facilities (SNFs), shorter LOS, and more frequent discharges to home, resulting in less costly post-acute care.

The second option provided by the requestor was to create a new MS–DRG by reassigning all cases in MS–DRG 470 reporting a hip replacement procedure (excluding those with an oxidized zirconium bearing surface implant) with a principal diagnosis of hip fracture and all hip replacement procedures with an oxidized zirconium bearing surface implant, with or without a principal diagnosis of hip fracture to the suggested new MS–DRG. The requestor stated that based on its own analysis, this new MS–DRG would have approximately 58,000 cases with an estimated relative weight between the current MS–DRGs for total joint arthroplasty (MS–DRGs 469 and 470) to reflect the increased resource consumption of total hip replacement procedures performed due to a hip fracture, while also reflecting a higher resource grouping for oxidized zirconium bearing surface implants used in total hip replacement procedures, and lastly, to reflect statistically significant reductions in revision of total hip replacement procedure rates.

The requestor also indicated that a new MS–DRG for total hip replacement procedures with a hip fracture would correspond to differentials recognized in the Comprehensive Care for Joint Replacement (CJR) model, which established a separate target 90-day episode price for total hip replacement procedures performed due to hip fracture cases, as these are typically higher severity patients with longer lengths of stay than hip replacement procedures absent a hip fracture.

The requestor conducted its own analysis of Medicare claims data (Q4 2017–Q3 2018) for total hip replacement procedures and compared cases with an oxidized zirconium bearing surface implant to cases without an oxidized zirconium bearing surface implant. The requestor reported that it found statistically reduced SNF costs, hospital length of stay, 90-day episode costs, and 55% decreased mortality at 180 days for the oxidized zirconium bearing surface implant cases. The requestor urged CMS to recognize this technology with a differentiated payment in the form of a new MS–DRG, based on its findings of excellent clinical outcomes for total hip replacement procedures that utilize an oxidized zirconium bearing surface implant.

The third option provided by the requestor was to reassign all cases reporting a total hip replacement procedure using an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture from MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) to MS–DRG 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement). The requestor stated this option would maintain the two existing MS–DRGs for total joint arthroplasty and would only involve moving a small

subset of cases (approximately 300) from MS–DRG 470 to MS–DRG 469.

The requestor acknowledged that the third option was more limited than the first two options, however, the requestor stated that it was the least disruptive since the two MS–DRGs and estimated relative weights would remain essentially the same. The requestor also stated that reassigning cases reporting a total hip replacement procedure using an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture from MS–DRG 470 to MS–DRG 469 would encourage hospitals to use these high-quality, proven implants.

The requestor also asserted that the third option focuses the suggested payment changes on the population of patients that benefit the most from the technology. According to the requestor, the analysis of Medicare claims data suggests that there is potential to improve care for the older population of patients who receive a total hip replacement by encouraging providers to use an oxidized zirconium bearing surface implant for hip fracture cases. In addition, the requestor stated that long-term Medicare solvency concerns impel consideration of incentives as a means to drive better outcomes at lower cost. Specifically, the requestor asserted that if all of the approximately 150,000 total hip replacement procedures performed annually in the U.S. for hip fracture achieved 90-day episode cost savings observed in Medicare claims for oxidized zirconium bearing surface implants, based on the requestor's analysis, potential annual savings of more than $650 million could be realized, in addition to longer-term savings achieved through reduced revisions.

The requestor also welcomed additional analysis by CMS of the claims data and consideration of alternative configurations that might better align patient severity, clinical value and payment.

As indicated by the requestor, October 1, 2017, new ICD–10–PCS procedure codes describing hip and knee replacement procedures with an oxidized zirconium bearing surface implant were created. The procedure codes are as follows:

ICD-10-PCS Code	Description
0SR9069	Replacement of right hip joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SR906A	Replacement of right hip joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SR906Z	Replacement of right hip joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRB069	Replacement of left hip joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRB06A	Replacement of left hip joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRB06Z	Replacement of left hip joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRC069	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRC06A	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRC06Z	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRD069	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRD06A	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRD06Z	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, open approach

We indicated in the FY 2021 IPPS/LTCH PPS proposed rule that we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 469 and 470 where hip and knee replacement procedures are currently assigned for cases reporting the use of an oxidized zirconium bearing surface implant to address the three options provided by the requestor.

To evaluate the first option provided by the requestor, we analyzed the cases reporting a total hip or total knee replacement procedure with an oxidized zirconium bearing surface implant in MS–DRG 470 to determine if a new MS–DRG is warranted. To evaluate the second option provided by the requestor, we analyzed the cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture and

cases reporting a total hip replacement procedure with an oxidized zirconium implant with or without a principal diagnosis of hip fracture in MS–DRG 470 to determine if a new MS–DRG is warranted. We referred the reader to Table 6P.1c associated with the proposed rule for a list of the procedure codes that describe a hip replacement without an oxidized zirconium bearing surface implant and to Table 6P.1e associated with the proposed rule for a list of the diagnosis codes describing a hip fracture that were provided by the requestor for consideration of options 2 and 3. To evaluate the third option provided by the requestor, we analyzed the cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant and a principal diagnosis of fracture in MS–DRG 470 to determine if the cases warrant reassignment to MS–DRG 469. Our findings are shown in the following table.

MS-DRGs for Total Hip and Knee Replacement Procedures with and without an Oxidized Zirconium Bearing Surface Implant with and without a Principal Diagnosis of Hip Fracture

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 469-All cases	25,701	5.9	$22,126
MS-DRG 470-All cases	386,221	2.3	$14,326
MS-DRG 470-Cases reporting a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant (Option 1)	18,898	2.1	$14,808
MS-DRG 470-Cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture (Option 2)	47,316	4.5	$16,077
MS-DRG 470-Cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture (Option 2)	7,241	1.9	$13,875
MS-DRG 470-Cases combined for Option 2	54,557	4.2	$15,785
MS-DRG 470-Cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture (Option 3)	316	4	$18,304

As shown in the table, there was a total of 25,701 cases with an average length of stay of 5.9 days and average costs of $22,126 in MS–DRG 469. For MS–DRG 470, there was a total of 386,221 cases with an average length of stay of 2.3 days and average costs of $14,326. Of those 386,221 cases in MS–DRG 470, there was a total of 18,898 cases reporting a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant with an average length of stay of 2.1 days and average costs of $14,808; a total of 47,316 cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture with an average length of stay of 4.5 days and average costs of $16,077; a total of 7,241 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture with an average length of stay of 1.9 days and average costs of $13,875; and a total of 316 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture with an average length of stay of 4 days and average costs of $18,304.

We noted that the data analysis performed to evaluate the first option provided by the requestor indicated that the 18,898 cases reporting a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant in MS–DRG 470 have a similar average length of stay (2.1 days versus 2.3 days) and similar average costs ($14,808 versus $14,326) compared to all the cases in MS–DRG 470. The results are also consistent with the requestor's findings that there were approximately 18,000 cases reporting a hip or knee replacement with an oxidized zirconium bearing surface implant. Based on the claims analysis, our clinical advisors stated that the data does not support creating a new MS–DRG for these procedures. We stated that our clinical advisors also believed that the characteristics of the patients

and resources used for a case that involves a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant are not clinically distinct from the characteristics of the patients and resources used for the cases reporting a total hip replacement or total knee replacement procedure without an oxidized zirconium bearing surface implant. Therefore, in consideration of the first option provided by the requestor, we proposed to not create a new MS–DRG for cases reporting a total hip or knee replacement procedure with an oxidized zirconium bearing surface implant.

The data analysis performed to evaluate the second option provided by the requestor indicated that the 47,316 cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 470 (4.5 days versus 2.3 days) and the average costs are higher when compared to all the cases in MS–DRG 470 ($16,077 versus $14,326). For the 7,241 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture, the average length of stay is shorter than the average length of stay for all the cases (1.9 days versus 2.3 days) and the average costs are slightly lower when compared to all the cases in MS–DRG 470 ($13,875 versus $14,326). Our analysis of the combined total number of cases identified for the second option provided by the requestor indicated that the 54,557 cases (47,316 + 7,241) have a longer average length of stay compared to the average length of stay for all the cases in MS–DRG 470 (4.2 days versus 2.3 days) and the average costs are slightly higher ($15,785 versus $14,326) when compared to all the cases in MS–DRG 470. The results are also consistent with the requestor's findings that there were approximately 58,000 cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture or a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture. We stated that our clinical advisors believed that the data does not support creating a new MS–DRG for the subset of cases as suggested by the requestor. They noted the variation in the volume (47,316 cases and 7,241 cases), average length of stay (4.5 days and 1.9 days), and the average costs ($16,077 and $13,875) for each subset of option 2 and that the total average cost for the combined cases identified for the second option ($15,785) is very similar to the costs of all the cases in MS–DRG 470 ($14,326). Therefore, in consideration of the second option provided by the requestor, we did not propose to create a new MS–DRG for cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture and cases reporting a total hip replacement procedure with an oxidized zirconium implant with or without a principal diagnosis of hip fracture.

The data analysis performed to evaluate the third option provided by the requestor indicated that the 316 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture have a longer average length of stay (4.0 days versus 2.3 days) and higher average costs ($18,304 versus $14,326) compared to all the cases in MS–DRG 470. The results are also consistent with the requestor's findings that there were approximately 300 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture. Our clinical advisors noted that while the data shows a longer length of stay and higher average costs for these cases under option 3, the analysis of the cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture under option 2 also demonstrated a longer length of stay and higher average costs. They therefore recommended we conduct further review specifically of those cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture, with or without an oxidized zirconium bearing surface implant.

As indicated in the proposed rule, based on the advice of our clinical advisors and in connection with the request for CMS to examine the claims data and consider alternative configurations, we performed additional analysis of those cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture for both MS–DRGs 469 and 470. We stated that the procedure codes for the hip replacement procedures included in this additional analysis are displayed in Table 6P.1d associated with the proposed rule and the diagnosis codes for hip fracture included in this additional analysis are displayed in Table 6P.1e associated with the proposed rule. Our findings are shown in the following table.

MS-DRGs for Total Hip and Knee Replacement Procedures with a Principal Diagnosis of Hip Fracture			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 469-All cases	25,701	5.9	$22,126
MS-DRG 469 – Cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture	14,163	7.2	$21,951
MS-DRG 470-All cases	386,221	2.3	$14,326
MS-DRG 470- Cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture	47,632	4.5	$16,092

As shown in the table, there was a total of 14,163 cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture with an average length of stay of 7.2 days and average costs of $21,951 in MS–DRG 469. There was a total of 47,632 cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture with an average length of stay of 4.5 days and average costs of $16,092 in MS–DRG 470. The average length of stay for the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture in MS–DRGs 469 and 470 were longer (7.2 days versus 5.9 days and 4.5 versus 2.3 days, respectively) compared to all the cases in their assigned MS–DRGs. The average costs of the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture in MS–DRG 469 were approximately $175 less when compared to the average costs of all cases in MS–DRG 469 ($21,951 versus $22,126) and slightly more for MS–DRG 470 ($16,092 versus $14,326). Our clinical advisors supported differentiating the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture from those cases without a hip fracture by assigning them to a new MS–DRG. They noted that clinically, individuals who undergo hip replacement following hip fracture tend to require greater resources for effective treatment than those without hip fracture. They further noted that the increased complexity associated with hip fracture patients can be attributed to the post traumatic state and the stress of pain, possible peri-articular bleeding, and the fact that this subset of patients, most of whom have fallen as the cause for their fracture, may be on average more frail than those who require hip replacement because of degenerative joint disease.

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.D.1.b. of the FY 2021 IPPS/LTCH PPS proposed rule and section II.E.1.b. of this final rule. We noted that, as shown in the table that follows, a three-way split of this base MS–DRG failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup and also failed to meet the criterion that there be at least a $2,000 difference in average costs between the CC and NonCC subgroup. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	14,163	7.2	$21,951
With CC	34,287	4.7	$16,500
Without CC/MCC	13,345	3.8	$15,042

We then applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups and found that all five criteria were met. We stated that for the proposed new MS–DRGs, there is at least (1) 500 cases in the MCC subgroup and 500 cases in the without MCC subgroup; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	14,163	7.2	$21,951
Without CC/MCC	47,632	4.5	$16,092

For FY 2021, we proposed to create new MS–DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) and new MS–DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture without MCC). We referred the reader to Table 6P.1d associated with this proposed rule for the list of procedure codes describing hip replacement procedures and to Table 6P.1e associated with the proposed rule for the list of diagnosis codes describing hip fracture diagnoses that we proposed to define in the logic for these new MS–DRGs.

Comment: Several commenters supported the proposal to create proposed new MS–DRGs 521 and 522 for patients undergoing a hip replacement due to a hip fracture. The commenters stated their belief that the proposed new MS–DRGs and payment rates will better match the resource utilization for these clinically distinct patients. Specifically, a commenter noted that it is appropriate to differentiate hip replacement cases based on whether the patient has a hip fracture since, as noted in clinical literature, total hip arthroplasty (THA) for hip fracture cases are subject to longer lengths of stay, and more postoperative complications, readmissions, reoperations, and mortality than THA cases performed for osteoarthritis of the hip. Another commenter stated that combining hip fractures in the current MS–DRGs 469 and 470 with planned hip replacement procedures fails to take into consideration and adequately compensate for the complex nature of and additional care fracture patients require. The commenter noted that hip fracture patients require an increased acute length of stay, often have more post traumatic stressors due to their fall and are on average frailer than those patients who choose to have an elective hip replacement, therefore, creating two new MS–DRGs would help to capture the differences in the care required and the cost between hip fracture patients and elective hip replacement patients. Another commenter expressed appreciation for CMS' effort to review the analysis and provide results of each option and alternative options in detail with the associated diagnosis and procedure codes in the proposed rule to define in the logic for the proposed new MS–DRGs. Based on the results, the commenter stated they agreed that differentiating the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture from those cases without a hip fracture by assigning them to a new MS–DRG would better align cases by average length of stay and average costs of cases, and lead to a more reasonable MS–DRG classification of these cases. Lastly, a commenter specifically expressed support for the establishment of the proposed new MS–DRGs, regardless of the type of bearing surface implant used in the joint replacement procedure.

However, a couple commenters who supported the concept of the proposal to create proposed new MS–DRGs 521 and 522 recommended that CMS not finalize the proposal until further analysis could be conducted. The commenters expressed concern that the relative weight and the average length of stay for proposed new MS–DRG 521 did not appear to align with clinical experience and underlying data since it is lower than the relative weight and average length of stay for MS–DRG 469. The commenters suggested that CMS re-evaluate and provide clarification on the data analysis.

A commenter expressed appreciation for the consideration CMS provided in response to the request to create MS–DRGs specifically for oxidized zirconium implants utilized in hip and knee replacement procedures. The commenter stated that although CMS' proposal did not explicitly focus on oxidized zirconium implants, an alternative option for the joint replacement procedures was examined and presented, resulting in the proposed new MS–DRGs 521 and 522. The commenter stated that these proposed MS–DRGs would improve distinguishing this subset of patients with a hip fracture who undergo a hip replacement procedure, however, the ability to differentiate meaningful parameters of care quality is not realized since the proposal treats all implants the same, despite what the commenter stated were the important clinical improvements demonstrated in the Medicare claims data for oxidized zirconium implants used for hip fracture patients. As a result, the commenter stated its belief that CMS should revise its proposal and adopt a specific MS–DRG for patients with a principal diagnosis of hip fracture receiving an oxidized zirconium bearing surface implant in a hip replacement procedure. According to the commenter, this would reflect an improvement over the proposed MS–DRGs 521 and 522, and best advance CMS policy and patient care objectives by creating incentives that appropriately encourage the use of a technology that has been shown to have substantial cost-saving and quality of care benefits. In addition, the commenter asserted that CMS stated a separate MS–DRG for oxidized zirconium is not warranted because certain criteria for establishing MS–DRG CC subgroups are not met. The commenter indicated CMS has broad statutory authority in the design of the Medicare inpatient payment system and is not required to limit its MS–DRG subgroups exclusively to be based on severity of co-morbidities or complications. The commenter remarked CMS should also not be limited to its five-step criteria for CC subgroups and by allowing for the creation of MS–DRG subgroups where there is clear evidence of a substantial clinical improvement will give CMS significantly greater flexibility to accomplish its goals of transformative quality improvement and cost-savings. The commenter stated that CMS has the ability and authority to make payment policy decisions that it believes will advance care and the Social Security Act grants CMS broad authority to establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. The commenter maintained that nothing in the statute prohibits CMS from creating MS–DRG groups or sub-groups based partly upon other important policy criteria, such as actual improved patient outcomes. According to the commenter, CMS should use its exceptions and adjustments authority to accomplish this objective. The commenter provided the example that although CMS did not propose to create a new MS–DRG for

oxidized zirconium implants, it could still adjust payment rates for inpatient stays involving such implants and accomplish similar results. The commenter expressed appreciation that the IPPS centrally organizes MS–DRGs on the basis of resource usage and clinical coherence, however, urged CMS to incorporate outcomes-based consideration. The commenter also contended that CMS has the opportunity to more fully realize the value of proven technologies by making incremental MS–DRG changes that lend access to the technologies shown to provide the most significant clinical benefits and signal to hospitals, surgeons, private payers, and others that CMS sees the value of these implants and wants to make sure Medicare beneficiaries can access these technologies. The commenter suggested that CMS consider MS–DRG subgroup requests that fall outside of the current five-step criteria for CC sub-groups, provided that requestors can demonstrate a substantial clinical improvement since this would allow the agency additional flexibility to make changes in MS–DRGs for technologies that demonstrate substantial clinical improvement based on lengthy track records of proven performance. The commenter noted how CMS utilizes the substantial clinical improvement criterion as part of assessing whether a new technology is eligible for a New Technology Add-On Payment or Transitional Pass-Through status and urged CMS to expand its use of this standard as an alternative pathway when evaluating certain MS–DRG subgroup requests. The commenter stated that in reviewing certain technologies associated with total joint replacement procedures, CMS should evaluate implants based on their ability to demonstrate significant reductions in long-term revision rates which are critical in studying improved patient outcomes and cost savings within the Medicare program. Additional data for revision rates from international joint replacement registries, reduced mortality rates from both international registries and Medicare claims data, and readmission rates from Medicare claims data was also provided by the commenter who asserted the information compels CMS to determine whether to finalize MS–DRGs that capture the broad category of hip fracture cases, or to create a narrower hip fracture MS–DRG based on strong outcomes differences observed in Medicare claims. The commenter asserted that because the data show strong results for hip fracture patients treated with an oxidized zirconium implant, CMS should also consider an exception and expand on proposed MS–DRGs 521 and 522 by creating a specific MS–DRG for hip fracture patients treated with an oxidized zirconium implant.

Lastly, the commenter expressed its appreciation for the analytical work and extensive consideration CMS provided to the request and acknowledged oxidized zirconium implants are only used in a very small portion of total hip replacement with hip fracture cases. The commenter stated its belief that the proposed MS–DRGs 521 and 522 would improve the ability to clinically distinguish hip fracture cases treated with a hip replacement from elective hip replacement procedures if CMS continues to believe a specific MS–DRG for hip fracture patients treated with an oxidized zirconium implant is not warranted.

Another commenter stated the proposal to create proposed new MS–DRGs 521 and 522 to account for differences in the cost of the THA procedure for a hip fracture appeared to be a neutral act in terms of cost. The commenter recommended that the proposal not be adopted as final policy since the current THA MS–DRGs 469 and 470 already provide similar reimbursement for the procedures through associated diagnostic codes, and the added expense of treating hip fractures is accounted for in the Comprehensive Care for Joint Replacement (CJR) Model. This commenter stated their belief that it would be inappropriate to make such a substantive change to the MS–DRG system without a strong body of evidence to support proposals which directly benefit one device over another. The commenter also stated they are not aware of any high-quality randomized controlled trials which report beneficial effects of the oxidized zirconium bearing surface. According to the commenter, any reported beneficial effect is most likely due to selection bias (that is, choosing younger, healthier patients for the oxidized zirconium bearings), rather than any real difference in performance. The commenter stated that this is true for registry data as well as clinical cohort studies. In addition, the commenter noted that among their society's hip replacement experts, the superiority of oxidized zirconium-alloy bearings is not a generally accepted fact. The commenter stated that they support higher reimbursement for hip replacements with a fracture in the existing MS–DRGs 469 and 470, however, they currently do not support creating the new MS–DRGs as proposed.

Response: We appreciate the commenters' support of the proposal to create proposed new MS–DRGs 521 and 522. We agree with the commenters that the proposed new MS–DRGs and payment rates will better match the resource utilization for these clinically distinct patients.

In response to the commenters who supported the concept of the proposal however recommended that CMS conduct further analysis for proposed new MS–DRG 521 because the proposed relative weight and average length of stay did not appear to align with clinical experience and underlying data in comparison to MS–DRG 469, we note that effective October 1, 2017 (FY 2018) the logic for MS–DRG 469 includes total ankle replacement procedures, therefore, the average length of stay, the average costs, and the relative weight of MS–DRG 469 continue to reflect the resource utilization associated with total ankle replacement procedures. In addition, total knee replacement procedures with a MCC are also included in the logic for MS–DRG 469.

The procedure codes identifying a total ankle replacement or total knee replacement are as follows:

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ICD-10-PCS Code	Description
0SRC069	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRC06A	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRC06Z	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRC07Z	Replacement of right knee joint with autologous tissue substitute, open approach
0SRC0EZ	Replacement of right knee joint with articulating spacer, open approach
0SRC0J9	Replacement of right knee joint with synthetic substitute, cemented, open approach
0SRC0JA	Replacement of right knee joint with synthetic substitute, uncemented, open approach
0SRC0JZ	Replacement of right knee joint with synthetic substitute, open approach
0SRC0KZ	Replacement of right knee joint with nonautologous tissue substitute, open approach
0SRC0L9	Replacement of right knee joint with medial unicondylar synthetic substitute, cemented, open approach
0SRC0LA	Replacement of right knee joint with medial unicondylar synthetic substitute, uncemented, open approach
0SRC0LZ	Replacement of right knee joint with medial unicondylar synthetic substitute, open approach
0SRC0M9	Replacement of right knee joint with lateral unicondylar synthetic substitute, cemented, open approach

0SRC0MA	Replacement of right knee joint with lateral unicondylar synthetic substitute, uncemented, open approach
0SRC0MZ	Replacement of right knee joint with lateral unicondylar synthetic substitute, open approach
0SRC0N9	Replacement of right knee joint with patellofemoral synthetic substitute, cemented, open approach
0SRC0NA	Replacement of right knee joint with patellofemoral synthetic substitute, uncemented, open approach
0SRC0NZ	Replacement of right knee joint with patellofemoral synthetic substitute, open approach
0SRT07Z	Replacement of right knee joint, femoral surface with autologous tissue substitute, open approach
0SRT0J9	Replacement of right knee joint, femoral surface with synthetic substitute, cemented, open approach
0SRT0JA	Replacement of right knee joint, femoral surface with synthetic substitute, uncemented, open approach
0SRT0JZ	Replacement of right knee joint, femoral surface with synthetic substitute, open approach
0SRT0KZ	Replacement of right knee joint, femoral surface with nonautologous tissue substitute, open approach
0SRV07Z	Replacement of right knee joint, tibial surface with autologous tissue substitute, open approach
0SRV0J9	Replacement of right knee joint, tibial surface with synthetic substitute, cemented, open approach
0SRV0JA	Replacement of right knee joint, tibial surface with synthetic substitute, uncemented, open approach
0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SRV0KZ	Replacement of right knee joint, tibial surface with nonautologous tissue substitute, open approach
0SRD069	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRD06A	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRD06Z	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRD07Z	Replacement of left knee joint with autologous tissue substitute, open approach
0SRD0EZ	Replacement of left knee joint with articulating spacer, open approach
0SRD0J9	Replacement of left knee joint with synthetic substitute, cemented, open approach
0SRD0JA	Replacement of left knee joint with synthetic substitute, uncemented, open approach
0SRD0JZ	Replacement of left knee joint with synthetic substitute, open approach

0SRD0KZ	Replacement of left knee joint with nonautologous tissue substitute, open approach
0SRD0L9	Replacement of left knee joint with medial unicondylar synthetic substitute, cemented, open approach
0SRD0LA	Replacement of left knee joint with medial unicondylar synthetic substitute, uncemented, open approach
0SRD0LZ	Replacement of left knee joint with medial unicondylar synthetic substitute, open approach
0SRD0M9	Replacement of left knee joint with lateral unicondylar synthetic substitute, cemented, open approach
0SRD0MA	Replacement of left knee joint with lateral unicondylar synthetic substitute, uncemented, open approach
0SRD0MZ	Replacement of left knee joint with lateral unicondylar synthetic substitute, open approach
0SRD0N9	Replacement of left knee joint with patellofemoral synthetic substitute, cemented, open approach
0SRD0NA	Replacement of left knee joint with patellofemoral synthetic substitute, uncemented, open approach
0SRD0NZ	Replacement of left knee joint with patellofemoral synthetic substitute, open approach
0SRU07Z	Replacement of left knee joint, femoral surface with autologous tissue substitute, open approach
0SRU0J9	Replacement of left knee joint, femoral surface with synthetic substitute, cemented, open approach
0SRU0JA	Replacement of left knee joint, femoral surface with synthetic substitute, uncemented, open approach
0SRU0JZ	Replacement of left knee joint, femoral surface with synthetic substitute, open approach
0SRU0KZ	Replacement of left knee joint, femoral surface with nonautologous tissue substitute, open approach
0SRW07Z	Replacement of left knee joint, tibial surface with autologous tissue substitute, open approach
0SRW0J9	Replacement of left knee joint, tibial surface with synthetic substitute, cemented, open approach
0SRW0JA	Replacement of left knee joint, tibial surface with synthetic substitute, uncemented, open approach
0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach
0SRW0KZ	Replacement of left knee joint, tibial surface with nonautologous tissue substitute, open approach

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We analyzed data from the September 2019 update of the FY 2019 MedPAR file for cases reporting a total ankle replacement procedure or a total knee replacement procedure in MS–DRG 469 for comparison to proposed MS–DRG 521. Our findings are shown in the following tables.

MS-DRG	Number of cases	Average Length of Stay	Average Costs
MS-DRG 469 - All cases	25,701	5.9	$22,126
Total Ankle Replacement Procedures	2,819	1.7	$22,327
Total Knee Replacement Procedures	4,617	4.9	$21,626

MS-DRG	Number of cases	Average Length of Stay	Average Costs
Proposed MS-DRG 521	14,163	7.2	$21,951

We found a total of 25,701 cases in MS–DRG 469 with an average length of stay of 5.9 days and average costs of $22,126. Of those 25,701 cases, we found a total of 2,819 cases reporting a total ankle replacement procedure with an average length of stay of 1.7 days and average costs of $22,327 and a total of 4,617 cases reporting a total knee replacement procedure with an average length of stay of 4.9days and average costs of $21,626.

As discussed in the proposed rule and shown in the table above, for proposed MS–DRG 521, the average length of stay is 7.2 days which is longer than the average length of stay of 5.9 days for MS–DRG 469, and the average costs for proposed MS–DRG 521 are slightly lower ($175) compared to the average costs of MS–DRG 469 ($21,951 versus $22,126, respectively).

The data demonstrates that the average costs of the total ankle replacement procedures in MS–DRG 469 are slightly higher than the average costs of all the cases in MS–DRG 469 ($22,327 versus $22,126). The proposal to reassign cases reporting a total hip replacement procedure with a principal diagnosis of a hip fracture from MS–DRG 469 to proposed new MS–DRG 521 includes the reassignment of 14,163 cases out of the 25,701 cases resulting in a total of 11,538 cases proposed to remain in MS–DRG 469. Of those 11,538 cases remaining in MS–DRG 469, a total of 2,819 cases reflect a higher utilization of resources, thereby continuing to impact the relative weight of MS–DRG 469 such that it is slightly higher than the proposed relative weight for proposed MS–DRG 521 (3.0844 versus 3.0634). Therefore, the data appears to reflect that the difference in the relative weights can be attributed to the fact that the total ankle replacement procedures continue to have an impact for MS–DRG 469.

In response to the commenter who stated that CMS should revise its proposal and adopt a specific MS–DRG for patients with a principal diagnosis of hip fracture receiving an oxidized zirconium bearing surface implant in a hip replacement procedure, we note that, our clinical advisors do not support the creation of a separate, specific MS–DRG for oxidized zirconium bearing surface implants for reasons previously discussed in the FY 2021 IPPS/LTCH PPS proposed rule. As the commenter stated in its own comments, CMS organizes MS–DRGs on the basis of resource usage and clinical coherence. Consistent with our annual process of evaluating MS–DRG classification requests, we performed a thorough review of the claims data for oxidized zirconium bearing surface implants utilized in a hip replacement procedure and provided a summary of that analysis, including input from our clinical advisors, as discussed in the proposed rule. Our clinical advisors believe that hip replacement procedures performed for a hip fracture demonstrate similar and predictable resource demands, regardless of the type of bearing surface implant used in the performance of the procedure. Therefore, we proposed to create new MS–DRGs 521 and 522, consistent with our efforts to continually refine the ICD–10 MS–DRGs while maintaining clinically coherent groups that also more accurately stratify Medicare patients with varying levels of severity. Therefore, with respect to the commenter's statement that CMS has broad authority to make policy changes, including the special exceptions and adjustment authority, we do not believe such changes would be appropriate or necessary for this group of hip replacement patients that receive an oxidized zirconium bearing surface implant. We can consider the commenter's suggestions to incorporate additional considerations into our analysis of MS–DRG classification requests in future rulemaking. We also wish to clarify for the commenter that the criteria to create subgroups within a base MS–DRG was not applied in evaluating the request to create a new MS–DRG. In other words, the criteria to create subgroups is only applied after the decision to propose to create a base MS–DRG is made.

Finally, in response to the commenter's statement that CMS should expand its use of the substantial clinical improvement standard as an alternative pathway when evaluating certain MS–DRG subgroup requests similar to the new technology add-on payment policy process, we will take this into future consideration.

In response to the commenter who stated their belief that it would be inappropriate to make a substantive change to the MS–DRG system without a strong body of evidence to support proposals which directly benefit one device over another and that they are not aware of any high-quality randomized controlled trials which report beneficial effects of the oxidized zirconium bearing surface, we wish to clarify that the CMS proposal did not involve proposing to directly benefit the oxidized zirconium bearing surface implant over other bearing surface implants. The CMS proposal presented was an alternative option to what the requestor submitted for CMS' consideration. Specifically, the CMS proposal was to group together all hip replacement procedures performed to treat a hip fracture, regardless of the type of bearing surface implant used, and the resulting MS–DRG assignment would be further differentiated based on the presence of a MCC, hence the proposal to create proposed new MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively).

After consideration of the comments we received, for the reasons previously discussed, we are finalizing our

proposal to create MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively) for FY 2021. We refer readers to table 6P.1d for the list of procedure codes describing hip replacements and table 6P.1e for the list of diagnosis codes describing hip fractures (available via the internet on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) that we are finalizing in the GROUPER logic for MS–DRGs 521 and 522.

In the FY 2021 IPPS/LTCH PPS proposed rule, we also noted that the Comprehensive Care for Joint Replacement (CJR) model includes episodes triggered by MS–DRG 469 with hip fracture and MS–DRG 470 with hip fracture. Given the proposal to create new MS–DRG 521 and MS–DRG 522, we sought public comment on the effect this proposal would have on the CJR model and whether to incorporate MS–DRG 521 and MS–DRG 522, if finalized, into the CJR model's proposed extension to December 31, 2023. As discussed in the CJR proposed rule ''Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing'' (85 FR 10516), we proposed to extend the duration of the CJR model. We stated that this extension, if finalized, would revise certain aspects of the CJR model including, but not limited to, the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements and the appeals process. Additionally, we stated that the CJR proposed rule would allow time to test the changes by extending the length of the CJR model through December 31, 2023, for certain participant hospitals. The comment period for the CJR proposed rule closed on June 23, 2020 (*85 FR 22978*). We intend to address the comments on the proposed rule and this solicitation in the Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing Final Rule. . In an interim final rule that we published in the April 6, 2020 **Federal Register**, we extended the duration of the CJR model through March 31, 2021, in light of the COVID–19 pandemic, to ensure continuity of CJR model operations in participant hospitals during the public health emergency so that we did not create any additional disruptions to the standard of care procedures hospitals have in place during this challenging time. Because the model will continue until at least March 31, 2021, we intend to adopt a policy in the CJR final rule that incorporates MS–DRG 521 and MS–DRG 522 into the CJR model as of the effective date of these new MS–DRGs. We believe such an approach would avoid disruption to the model for the remainder of PY5 (as extended) and thereafter, if our proposal to extend the CJR model to December 31, 2023 is finalized.

8. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

a. Kidney Transplants

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32510), we received two separate but related requests to review the MS–DRG assignment for procedures describing the transplantation of kidneys. The first request was to designate kidney transplants as a Pre-MDC MS–DRG in the same manner that other organ transplants are. The requestor performed its own analysis and stated that it found that cases with a principal diagnosis from MDC 05 (Diseases and Disorders of the Circulatory System), for example I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease), reported with a kidney transplant from MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), grouped to MS–DRG 981(Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC). The requestor stated it did not appear appropriate that a kidney transplant would group to MS–DRG 981 when diagnosis code I13.2 is a legitimate principal diagnosis for this procedure. This requestor also suggested that if there was a proposal for designating the MS–DRG for kidney transplants as a Pre-MDC MS–DRG, that a severity level split should also be considered.

As discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42128 through 42129), during our review of cases that group to MS–DRGS 981 through 983, we noted that when procedures describing transplantation of kidneys (ICD–10–PCS procedure codes 0TY00Z0 (Transplantation of right kidney, allogeneic, open approach) and 0TY10Z0 (Transplantation of left kidney, allogeneic, open approach) are reported in conjunction with ICD–10–CM diagnosis codes in MDC 05 (Diseases and Disorders of the Circulatory System), the cases group to MS–DRGs 981 through 983. For the reasons discussed, we proposed to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 05. As summarized in the FY 2020 IPPS/LTCH PPS final rule, commenters opposed our proposal to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 05. Commenters suggested that CMS instead assign these cases to MS–DRG 652, noting that the length of stay for the vast majority of kidney transplant cases involving serious cardiac conditions approximates the length of stay for kidney transplants in general. After consideration of public comments, we did not finalize our proposal to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 05. We stated that we believed it would be appropriate to take additional time to review the concerns raised by commenters consistent with the President's Executive Order on Advancing American Kidney Health (see *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/*). Accordingly, cases reporting a principal diagnosis in MDC 05 with a procedure describing kidney transplantation (that is, procedure code 0TY00Z0 or 0TY10Z0) continue to group to MS–DRGs 981 through 983 under the ICD–10 MS–DRGs Version 37, effective October 1, 2019.

In the proposed rule, we stated in response to these public comments and the request we received on this topic for FY 2021 consideration, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRG 652. In MS–DRG 652, there were 11,324 cases reporting one of the procedure codes listed describing a kidney transplant procedure, with an average length of stay of 6 days and average costs of $25,424.

ICD-10-PCS Code	Code Description
0TY00Z0	Transplantation of right kidney, allogeneic, open approach
0TY00Z1	Transplantation of right kidney, syngeneic, open approach
0TY00Z2	Transplantation of right kidney, zooplastic, open approach
0TY10Z0	Transplantation of left kidney, allogeneic, open approach
0TY10Z1	Transplantation of left kidney, syngeneic, open approach
0TY10Z2	Transplantation of left kidney, zooplastic, open approach

We then analyzed claims data for cases reporting one of the procedure codes listed describing the transplantation of kidney reported in MS–DRGs 981, 982, and 983. We did not find any such cases in MS–DRG 983.

MS-DRGs 981 and 982: Cases Reporting Procedures Describing Kidney Transplants			
ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
0TY00Z0	264	6.7	$27,344
0TY00Z1	2	19.5	$173,011
0TY10Z0	99	6.5	$25,254
0TY10Z1	1	13	$37,803

Of the 366 cases reporting procedures describing kidney transplants in MS–DRGs 981 and 982, all of the cases reported a principal diagnosis from MDC 05. The diagnoses reported are reflected in the table.

MDC 05 Principal Diagnoses Reported with Procedure Codes for Kidney Transplant in MS-DRGs 981 and 982				
ICD-10-CM Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
I11.0	Hypertensive heart disease with heart failure	1	5.0	$15,782
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	5	5.9	$24,236
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	358	6.2	$27,204
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	1	6.0	$22,355
I77.89	Other specified disorders of arteries and arterioles	1	4.0	$34,358

Our clinical advisors reviewed these data. As indicated previously, in MS–DRG 652, there were 11,324 cases reporting one of the procedure codes listed describing a kidney transplant procedure, with an average length of stay of 6 days and average costs of $25,424. Our clinical advisors noted that the average costs for cases reporting transplantation of kidney with a diagnosis from MDC 05 listed previously are generally similar to the average costs of cases in MS–DRG 652. The diagnoses assigned to MDC 05 reflect conditions associated with the circulatory system. We stated that our clinical advisors agreed that although these diagnoses might also be a reasonable indication for kidney transplant procedures, it would not be appropriate to move these diagnoses into MDC 11 because it could inadvertently cause cases reporting these same MDC 05 diagnoses with a circulatory system procedure to be assigned to an unrelated MS–DRG.

To further examine the impact of moving MDC 05 diagnoses into MDC 11, we analyzed claims data for cases reporting a circulatory system O.R. procedure and MDC 05 ICD–10–CM diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease). Diagnosis code I13.2 was selected since this diagnosis was the MDC 05 diagnosis most frequently reported with kidney transplant procedures. Our findings are reflected in the following table:

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Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of I13.2

MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
215	Other Heart Assist System Implant	66	15.3	$92,229
216	Cardiac Valve And Other Major Cardiothoracic Procedures With Cardiac Catheterization with MCC	34	23.5	$101,406
219	Cardiac Valve And Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	14	23.4	$83,807
222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC	64	11.8	$67,663
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	126	9.9	$55,107
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	2	7.5	$52,521
228	Other Cardiothoracic Procedures with MCC	48	16.0	$60,199
231	Coronary Bypass with PTCA with MCC	1	16.0	$122,757
233	Coronary Bypass with Cardiac Catheterization with MCC	38	20.8	$92,315
235	Coronary Bypass without Cardiac Catheterization with MCC	13	13.8	$53,786
239	Amputation For Circulatory System Disorders Except Upper Limb And Toe with MCC	71	18.0	$43,665
242	Permanent Cardiac Pacemaker Implant with MCC	140	13.0	$45,094
243	Permanent Cardiac Pacemaker Implant with CC	1	8.0	$47,133
245	AICD Generator Procedures	50	9.8	$49,604
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent With MCC Or 4+ Arteries Or Stents	632	8.3	$31,550

Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of I13.2				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
248	Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent With MCC Or 4+ Arteries Or Stents	28	9.1	$30,088
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC	52	9.5	$26,888
252	Other Vascular Procedures with MCC	1,392	10.1	$27,495
253	Other Vascular Procedures with CC	5	5.6	$9,738
255	Upper Limb And Toe Amputation For Circulatory System Disorders with MCC	28	11.9	$23,691
258	Cardiac Pacemaker Device Replacement with MCC	8	4.1	$15,210
260	Cardiac Pacemaker Revision Except Device Replacement with MCC	22	8.9	$27,198
263	Vein Ligation And Stripping	3	11.0	$33,860
264	Other Circulatory System O.R. Procedures	1,185	10.4	$27,612
265	AICD Lead Procedures	3	11.3	$30,528
266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC	51	18.7	$88,325
268	Aortic And Heart Assist Procedures Except Pulsation Balloon with MCC	4	13.5	$40,885
270	Other Major Cardiovascular Procedures with MCC	223	13.7	$45,112
273	Percutaneous Intracardiac Procedures with MCC	62	9.9	$31,193
	Total Cases	4,366		

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As shown in the table, if we were to move diagnosis code I13.2 to MDC 11, 4,366 cases would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence. Therefore, as an alternate option, we proposed to modify the GROUPER logic for MS–DRG 652 by allowing the presence of a procedure code describing transplantation of the kidney to determine the MS–DRG assignment independent of the MDC of the principal diagnosis in most instances. The logic for MDC 24 (Multiple Significant Trauma) and MDC 25 (Human Immunodeficiency Virus Infections) will remain unchanged, meaning there would be two exceptions to the modification of the GROUPER logic for MS–DRG 652. If a principal diagnosis of trauma and at least two significant traumas of different body sites are present, the appropriate MS–DRG in MDC 24 would be assigned based on the principal diagnosis and procedures reported, instead of MS–DRG 652. Also, if either a principal diagnosis of HIV infection or a secondary diagnosis of HIV infection with a principal diagnosis of a significant HIV related condition are present, the appropriate MS–DRG in MDC 25 would be assigned based on the principal diagnosis and procedures reported instead of MS–DRG 652. The diagram found towards the end of this discussion illustrates how the MS–DRG logic for MS–DRG 652 (Kidney Transplant) would function.

We stated we recognized MS–DRG 652 is one of the only transplant MS–DRGs not currently defined as a Pre-MDC. Pre-MDCs were an addition to Version 8 of the Diagnosis Related Groups. This proposal was the first departure from the use of principal diagnosis as the initial variable in DRG and subsequently MS–DRG assignment. For Pre-MDC DRGs, the initial step in DRG assignment is not the principal diagnosis, but instead certain surgical procedures with extremely high costs such as heart transplant, liver transplant, bone marrow transplant, and tracheostomies performed on patients on long-term ventilation. When added in Version 8, these types of services were viewed as being very resource intensive. Our clinical advisors have noted, however, that treatment practices have shifted since the inception of Pre-MDCs. We stated that the current proposed refinements to MS–DRG 652 represent the first step in investigating how we may consider introducing this concept of allowing certain procedures to affect the MS–DRG assignment regardless of the MDC from which the diagnosis is reported in the future, with the possibility of removing the Pre-MDC category entirely. In other words, we would consider having the resource intensive procedures currently assigned to the Pre-MDC MS–DRGs determine assignment to MS–DRGs within the clinically appropriate MDC. We are making concerted efforts to continue refining the ICD–10 MS–DRGs and we believe that it is important to include the Pre-MDC category as part of our comprehensive review.

Comment: Commenters agreed with CMS' proposal to modify the GROUPER logic for MS–DRG 652 (Kidney Transplant) to allow the presence of a procedure code describing

transplantation of the kidney to determine the MS–DRG assignment independent of the MDC. A commenter also stated they agreed that CMS should consider having the resource-intensive procedures currently assigned to the Pre-MDC MS–DRGs determine assignment to MS–DRGs with the ultimate goal of perhaps being able to eliminate the Pre-MDC category entirely.

Response: We appreciate the commenters' support of the proposal and CMS' plan to include the Pre-MDC category as part of our comprehensive, systematic review of the ICD–10–PCS procedure codes. After consideration of the public comments we received, we are finalizing the proposal to modify the GROUPER logic for MS–DRG 652 to allow the presence of a procedure code describing transplantation of the kidney to determine the MS–DRG assignment independent of the MDC of the principal diagnosis except in the two instances noted above.

We stated in the proposed rule, in response to the request for a severity level split, since the request to designate kidney transplants as a Pre-MDC MS–DRG did not involve a revision of the existing GROUPER logic for MS–DRG 652, we applied the five criteria as described in section II.E.1.b. of the preamble of this final rule to determine if it would be appropriate to subdivide cases currently assigned to MS–DRG 652 into severity levels. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 652 using the September 2018 update of the FY 2018 MedPAR file and the September 2019 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2021. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	11,324	7,567	3,401	356	$25,424	$26,724	$23,085	$20,148	$25,596	$22,806
2018	11,473	7,519	3,490	464	$24,086	$ 25,330	$22,094	$18,931	$24,304	$21,723

We applied the criteria to create subgroups for the three-way severity level split. As discussed in section II.D.1.b. of the proposed rule and section II.E.1.b. of this final rule, we proposed, and are finalizing, the expansion of the previously listed criteria to also include the NonCC group. We found that the criterion that there be at least a 20% difference in average costs between subgroups failed for the average costs between the MCC and CC subgroups based on the data in both the FY 2018 and FY 2019 MedPAR files. The criterion that there be at least 500 cases for each subgroup also was not met, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 356 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2019 MedPAR file and only 464 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2018 MedPAR file. We then applied the criteria to create subgroups for the two-way severity level splits and found that the criterion that there be at least a 20 percent difference in average costs between the ''with MCC'' subgroup and the ''without MCC'' group failed for both years. The criterion that there be at least a 3-percent reduction in cost variance between the ''with CC/MCC'' and ''without CC/MCC'' subgroups also failed for both years, indicating that the current base MS–DRG 652 maintains the overall accuracy of the IPPS payment system. The claims data do not support a three-way or a two-way severity level split for MS–DRG 652, therefore for FY 2021, we did not propose to subdivide MS–DRG 652 into severity levels.

Comment: A commenter supported our proposal and expressed appreciation for CMS's examination of the GROUPER logic for DRG 652.

Response: We appreciate the commenters' support.

After consideration of public comments, we are finalizing the proposal to not subdivide MS–DRG 652 into severity levels. We refer the reader to section II.E.1.b. of this final rule for the comments regarding our proposal to expand the previously listed subgroup criteria to also include the NonCC group, as well as our finalization of that proposal.

As discussed in the proposed rule and earlier in this section we received two separate but related requests. The second request was that a new MS–DRG be created for kidney transplant cases where the patient received dialysis during the inpatient stay and after the date of the transplant. According to the requestor, transplant hospitals incur higher costs related to post-transplant care of patients who receive kidneys from ''medically complex donors'' (defined by the requestor as coming from organ donors over aged 60 and donors after circulatory death). The requestor also stated that their research indicated that studies consistently identified organ donors over the age of 60 and donors after circulatory death as the most significant areas for growth in increasing the number of organ transplantations, but this growth is hampered by the underutilization of these types of organs. The requestor performed its own data analysis and stated that total standardized costs were 32 percent higher for cases where the beneficiary received dialysis during the inpatient stay and after the date of transplant compared to all other kidney transplant cases currently in MS–DRG 652 (Kidney Transplant), with the additional costs serving as a disincentive to the use of viable kidneys for donation. The requestor asserted that this financially disadvantages transplant centers from using such organs, contributing to the kidney discard rate.

The following ICD–10–PCS procedure codes identify the performance of hemodialysis.

ICD-10-PCS Code	Code Description
5A1D70Z	Performance of urinary filtration, intermittent, less than 6 hours per day
5A1D80Z	Performance of urinary filtration, prolonged intermittent, 6-18 hours per day
5A1D90Z	Performance of urinary filtration, continuous, greater than 18 hours per day

We stated that we acknowledged that the request was to review the costs of dialysis performed after kidney transplantation during the same inpatient admission, however our clinical advisors pointed out, that while not routine, it is not uncommon for a patient to require dialysis while admitted for kidney transplantation before the procedure is performed due to factors related to the availability of the organ, nor is it uncommon for a kidney that has been removed from the donor, transported, and then implanted to require dialysis before it returns to optimal function. Therefore, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRG 652 and compared the results to cases representing kidney transplantation with dialysis performed during the same inpatient admission either before or after the date of kidney transplantation. The following table shows our findings:

Kidney Transplant Procedures			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 652 - All cases	11,324	6.0	$25,424
MS-DRG 652 - Cases reporting hemodialysis	3,254	7.6	$30,606

As shown by the table, for MS–DRG 652, we identified a total of 11,324 cases, with an average length of stay of 6.0 days and average costs of $25,424. Of the 11,324 cases in MS–DRG 652, there were 3,254 cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant with an average length of stay of 7.6 days and average costs of $30,606. Our clinical advisors noted that the average length of stay and average costs of cases in MS–DRG 652 describing the performance of hemodialysis in an admission where the patient received a kidney transplant were higher than the average length of stay and average costs for all cases in the same MS–DRG.

We stated in further analyzing this issue, noting that patients can require a simultaneous pancreas/kidney transplant procedure, we also examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in Pre-MDC MS–DRG 008 (Simultaneous Pancreas/Kidney Transplant) and compared the results to cases representing simultaneous pancreas/kidney transplantation with dialysis performed during the same inpatient admission either before or after the date of kidney transplantation. The following table shows our findings:

Pre-MDC MS-DRG 008 Simultaneous Pancreas/Kidney Transplant Procedures			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 008 - All cases	374	10.9	$41,926
MS-DRG 008 - Cases reporting hemodialysis	84	13.4	$49,001

As shown by the table, for Pre-MDC MS–DRG 008, we identified a total of 374 cases, with an average length of stay of 10.9 days and average costs of $41,926. Of the 374 cases in Pre-MDC MS–DRG 008, there were 84 cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant with an average length of stay of 13.4 days and average costs of $49,001. We stated our clinical advisors again noted that the average length of stay and average costs of cases in Pre-MDC MS–DRG 008 describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant were higher than the average length of stay and average costs for all cases in the same Pre-MDC MS–DRG.

In the proposed rule, we stated our clinical advisors believe that these hemodialysis procedures either performed before or after kidney transplant or before or after simultaneous pancreas/kidney transplant contribute to increased resource consumption for these

transplant patients. While there is not a large number of cases describing a simultaneous pancreas/kidney transplant with hemodialysis procedures either performed before or after transplant represented in the Medicare data, and we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, we stated we believe creating separate MS–DRGs for these cases would appropriately address the differential in resource consumption consistent with the President's Executive Order on Advancing American Kidney Health (see *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/*). For these reasons, we proposed to create new MS–DRGs for the performance of hemodialysis during an admission where the patient received a kidney transplant or simultaneous pancreas/kidney transplant.

As stated in the proposed rule, to compare and analyze the impact of our suggested modifications, we ran a simulation using the Version 37 ICD–10 MS–DRG GROUPER and the claims data from the September 2019 update of the FY 2019 MedPAR file. The following table reflects our findings for all 3,254 cases representing kidney transplantation with dialysis performed during the same inpatient admission either before or after the date of kidney transplantation with a two-way severity level split.

New MS-DRGs for Kidney Transplant with Hemodialysis			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG XXX (Kidney Transplant with Hemodialysis with MCC)	2,195	8.0	$32,360
MS-DRG XXX (Kidney Transplant with Hemodialysis without MCC)	1,059	6.8	$26,972

As shown in the table, there was a total of 2,195 cases for the kidney transplant with hemodialysis with MCC subgroup, with an average length of stay of 8.0 days and average costs of $32,360. There was a total of 1,059 cases for the kidney transplant with hemodialysis without MCC subgroup, with an average length of stay of 6.8 days and average costs of $26,972. We applied the criteria to create subgroups for the two-way severity level split for the proposed MS–DRGs, including our expansion of the criteria to also include the nonCC group, and found that all five criteria were met. For the proposed MS–DRGs, there is (1) at least 500 cases in the MCC subgroup and in the without MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup and in the without MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the without MCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the without MCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

For the cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant, we identified a total of 84 cases, so the criterion that there are at least 500 or more cases in any subgroup could not be met. Therefore, for FY 2021, we did not propose to subdivide the proposed new Pre-MDC MS–DRG for the performance of hemodialysis in an admission where the patient received a simultaneous pancreas/kidney transplant into severity levels.

In summary, in the FY 2021 proposed rule, taking into consideration that it clinically requires greater resources to perform hemodialysis during an admission where the patient received a kidney or simultaneous pancreas/kidney transplant, we proposed to create a new Pre-MDC MS–DRG for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant. We also proposed to create two new MS–DRGs with a two-way severity level split for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11. These proposed new MS–DRGs are new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis), new MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC) and new MS–DRG 651 (Kidney Transplant with Hemodialysis without MCC). We proposed to add the procedure codes from current Pre-MDC MS–DRG 008 to the proposed new Pre-MDC MS–DRG 019 with the procedure codes describing a hemodialysis procedure. Similarly, we also proposed to add the procedure codes from current MS–DRG 652 to the proposed new MS–DRGs 650 and 651 with the procedure codes describing a hemodialysis procedure. In the proposed rule, we noted that the procedure codes describing hemodialysis procedures are designated as non-O.R. procedures, therefore, as part of the logic for these proposed new MS–DRGs, we also proposed to designate these codes as non-O.R. procedures affecting the MS–DRG.

Comment: Many commenters supported CMS' proposal. Commenters stated that the establishment of new MS–DRGs for kidney and simultaneous pancreas/kidney transplants with hemodialysis will increase the number of viable kidneys for transplantation and decrease the kidney discard rate by reducing the financial disincentive for using kidneys from medically complex donors. A few commenters stated they appreciate CMS' recognition of the higher cost involved in these cases and the effort to make kidney transplant services more accessible by aligning payment rates with the relative cost of services for kidney transplants. A commenter stated the proposed creation of two new MS–DRGs for kidney transplant cases with hemodialysis—one for cases with major complications and comorbidities (MCC) and one for cases without MCC, strengthens transplant programs and increases

patient access to this vital medical service. Another commenter stated the inclusion of a MCC subgroup for kidney transplant with hemodialysis is vital given the documented increase in the complexity of transplant patients. One commenter specifically stated they strongly support efforts to ensure that kidney transplant MS–DRGs better reflect the cost of all associated care.

Response: We appreciate the commenters' support.

Comment: A few commenters opposed this proposal. One commenter stated they are concerned that the proposal would decrease Medicare payment for all kidney transplants not requiring post-transplant dialysis and were against including components in the proposal that would result in a reduction in inpatient payment for kidney transplant in any category. Another commenter stated they were concerned that CMS will extract money from existing MS–DRG 652 and Pre-MDC MS–DRG 008 to pay for the proposed new MS–DRGs. A different commenter stated their facility has a low volume of admissions with both hemodialysis and kidney transplant performed, with only approximately 21 out of a total of 110 kidney transplants having such a combination, and therefore would be adversely affected should this proposal be finalized.

Response: We appreciate the commenters' concerns, however as we have stated in prior rulemaking, the MS–DRGs are a classification system intended to group together those diagnoses and procedures with similar clinical characteristics and utilization of resources. We continue to believe that consistent with this classification system, the proposed new MS–DRGs would improve clinical coherence while appropriately addressing the differential in resource consumption for cases where hemodialysis is performed during an admission where the patient receives a kidney or simultaneous pancreas/kidney transplant. Each year, we calculate the relative weights by dividing the average cost for cases within each MS–DRG by the average cost for cases across all MS–DRGs. It is to be expected that when MS–DRGs are restructured, resulting in a different case-mix within the new MS–DRGs, the relative weights of the MS–DRGs will change as a result. We refer readers to section II.E.2. of the preamble of this final rule for a discussion of the relative weight calculations.

Therefore, after consideration of the public comments received, and for the reasons stated above, we are finalizing our proposal to create new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis) for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant. We are also finalizing our proposal to create new MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC) and new MS–DRG 651 (Kidney Transplant with Hemodialysis without MCC) for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11. Accordingly, we are also finalizing our proposal to designate procedure codes 5A1D70Z, 5A1D80Z, and 5A1D90Z that describe hemodialysis as non-O.R. procedures affecting the MS–DRG.

The diagram illustrates how the MS–DRG logic for Kidney Transplants will function. The diagram (Diagram 1.), which is the same Diagram 1 included in the proposed rule, begins by asking if the criteria for a Pre-MDC MS–DRG is met. If yes, the logic asks if the criteria for Pre-MDC MS–DRGs 018, 001–006, 014 or 007 is met. If yes, the logic directs the case to either Pre-MDC MS–DRG 018, 001–006, 014 or 007 based on the principal diagnosis and/or procedures reported. If no, the logic asks if there is a simultaneous pancreas/kidney transplant with a qualifying diagnosis reported on the claim. If no, the logic directs the case to either Pre-MDC MS–DRGs 016, 017, or 010–013 based on the principal diagnosis and/or procedures reported. If yes, the logic asks if there was a hemodialysis procedure reported on the claim. If yes, the logic assigns the case to new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis). If no, the logic assigns the case to existing Pre-MDC MS–DRG 008 (Simultaneous Pancreas/Kidney Transplant).

If the criteria for a Pre-MDC MS–DRG were not met at the first step, the GROUPER logic asks if there was a principal diagnosis of trauma and at least two significant traumas of different body sites. If yes, the logic directs the case to the appropriate MS–DRG in MDC 24 based on the principal diagnosis and procedures reported. If no, the logic asks if there was either a principal diagnosis of HIV infection or a secondary diagnosis of HIV infection with a principal diagnosis of a significant HIV related condition. If yes, the logic directs the case to the appropriate MS–DRG in MDC 25 based on the principal diagnosis and procedures reported. If no, the logic asks if there is kidney transplant procedure reported on the claim. If no, the logic directs the case to the appropriate MDC and MS–DRG based on the principal diagnosis and procedures reported. If yes, the logic asks if there was a hemodialysis procedure reported on the claim. If yes, the logic assigns the case to new MS–DRGs 650 or 651 (Kidney Transplant with Hemodialysis with MCC or without MCC, respectively). If no, the logic assigns the case to existing MS–DRG 652 (Kidney Transplant).

We also received public comments regarding a number of kidney and hemodialysis related MS–DRG issues that were outside the scope of the proposals included in the FY 2021 IPPS/LTCH PPS proposed rule. These comments were as follows:

- One commenter requested that CMS establish a new MS–DRG for Continuous Renal Replacement Therapy (CRRT).
- One commenter requested that CMS review other transplant cases that end up in MS–DRGs 981 through 983 for reassignment to a more appropriate MS–DRG.
- Two commenters requested that CMS evaluate and make modifications to any MS–DRG related to the delivery of dialysis.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.E.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classification to submit these comments no later than November 1, 2020 so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

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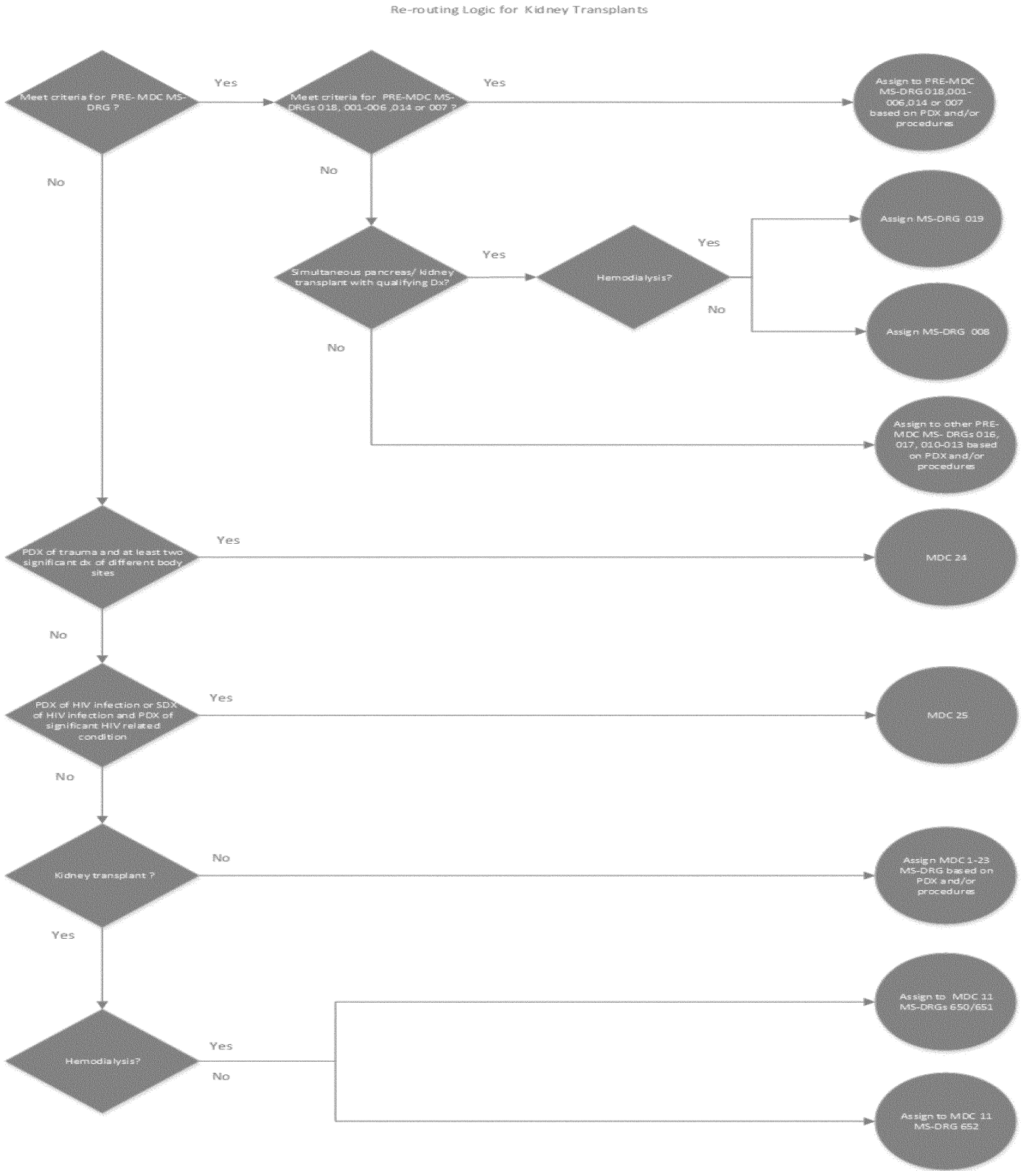
Diagram 1.


Re-routing Logic for Kidney Transplants
Meet criteria for PRE- MDC MS-DRG ?
Yes
Meet criteria for PRE-MDC MS-DRGs 018, 001-006 ,014 or 007 ?
Yes
Assign to PRE-MDC MS-DRG 018,001-006,014 or 007 based on PDX and/or procedures
No
No
Simultaneous pancreas/ kidney transplant with qualifying Dx?
Yes
Hemodialysis?
Yes
Assign MS-DRG 019
No
Assign MS-DRG 008
No
Assign to other PRE-MDC MS- DRGs 016, 017, 010-013 based on PDX and/or procedures
PDX of trauma and at least two significant dx of different body sites
Yes
MDC 24
No
PDX of HIV infection or SDX of HIV infection and PDX of significant HIV related condition
Yes
MDC 25
No
Kidney transplant ?
No
Assign MDC 1-23 MS-DRG based on PDX and/or procedures
Yes
Hemodialysis?
Yes
Assign to MDC 11 MS-DRGs 650/651
No
Assign to MDC 11 MS-DRG 652

b. Addition of Diagnoses to Other Kidney and Urinary Tract Procedures Logic

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32519), we received a request to add 29 ICD–10–CM diagnosis codes to the list of principal diagnoses assigned to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The list of 29 ICD–10–CM diagnosis codes submitted by the requestor, as well as their current MDC assignments, are found in the table:

ICD-10-CM Code	Code Description	MDC
T86.11	Kidney transplant rejection	11
T86.12	Kidney transplant failure	11
T86.13	Kidney transplant infection	11
T86.19	Other complication of kidney transplant	11
E10.21	Type 1 diabetes mellitus with diabetic nephropathy	11
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	11
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication	11
E11.21	Type 2 diabetes mellitus with diabetic nephropathy	11
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	11
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication	11
E13.21	Other specified diabetes mellitus with diabetic nephropathy	11
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease	11
E13.29	Other specified diabetes mellitus with other diabetic kidney complication	11
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease	05
T80.211A	Bloodstream infection due to central venous catheter, initial encounter	05
T80.212A	Local infection due to central venous catheter, initial encounter	05
T80.218A	Other infection due to central venous catheter, initial encounter	05
T82.41XA	Breakdown (mechanical) of vascular dialysis catheter	05
T82.42XA	Displacement of vascular dialysis catheter	05
T82.43XA	Leakage of vascular dialysis catheter	05
T82.49XA	Other complication of vascular dialysis catheter	05
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter	05
T82.818A	Embolism due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.828A	Fibrosis due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.838A	Hemorrhage due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.848A	Pain due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.858A	Stenosis of other vascular prosthetic devices, implants and grafts, initial encounter	05
T82.868A	Thrombosis due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.898A	Other specified complication of vascular prosthetic devices, implants and grafts, initial encounter	05

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The requestor stated that by adding the codes listed, cases reporting principal diagnosis codes describing complications of dialysis access sites and principal diagnosis codes describing kidney disease in the setting of diabetes or hypertension, would group to MS–DRGs 673, 674, and 675 when a TIVAD or tunneled vascular access device is inserted. The requestor stated that patients who have kidney transplant complications or dialysis catheter complications typically also have chronic kidney disease, end stage renal disease (ESRD) or resolving acute tubular necrosis (ATN) but ICD–10–CM coding guidelines require a complication code to be sequenced first. The requester stated that when reporting a diagnosis code describing ESRD and diabetes, a diabetes code from ICD–10–CM Chapter 4 (Endocrine, Nutritional and Metabolic Diseases) must be sequenced first and when coding ESRD, hypertension, and heart failure, the combination code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease) must be sequenced first per coding guidelines. The requestor pointed out that code I13.11 (Hypertensive heart and chronic kidney disease without heart failure with stage 5 CKD or ESRD) is currently one of the qualifying principal diagnoses in MS–DRGs 673, 674, and 675 when reported with procedure codes describing the insertion of TIVADs or tunneled vascular access devices; therefore, according to the requestor, diagnosis code I13.2 should reasonably be added.

As discussed in the proposed rule, to begin our analysis, we reviewed the GROUPER logic for MS–DRGs 673, 674, and 675 including the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with

procedure codes for the insertion of tunneled or totally implantable vascular access devices. As discussed in the FY 2003 IPPS/LTCH PPS final rule (67 FR 49993 through 49994), the procedure code for the insertion of totally implantable vascular access devices was added to the GROUPER logic of DRG 315 (Other Kidney and Urinary Tract O.R. Procedures), the predecessor DRG of MS–DRGs 673, 674, and 675, when combined with principal diagnoses specifically describing renal failure, recognizing that inserting these devices as an inpatient procedure for the purposes of hemodialysis can lead to higher average charges and longer lengths of stay for those cases.

We next reviewed the 29 ICD–10–CM codes submitted by the requestor. In the proposed rule, we stated our clinical advisors noted that ICD–10–CM diagnosis codes E10.21, E11.21, and E13.21 describing diabetes mellitus with diabetic nephropathy; codes E10.29, E11.29, and E13.29 describing diabetes mellitus with other diabetic kidney complication; T80.211A, T80.212A, and T80.218A describing infection due to central venous catheters; and codes T82.7XXA, T82.818A, T82.828A, T82.838A, T82.848A, T82.858A, T82.868A, and T82.898A describing complications of cardiac and vascular prosthetic devices, implants and grafts, are not necessarily indicative of a patient having renal (kidney) failure requiring the insertion of a TIVAD or a tunneled vascular access device to allow access to the patient's blood for hemodialysis purposes. TIVADs and tunneled vascular access devices are widely used to provide central venous access for the administration of intravenous antibiotics, chemotherapeutic agents, parenteral nutrition and other treatments. They are used in a variety of disease groups, and in both children and adults. We stated in the proposed rule that as such, our clinical advisors do not support adding these diagnoses to the list of principal diagnosis codes in MS–DRG 673, 674, and 675 when reported with procedure codes describing the insertion of TIVADs and tunneled vascular access devices. They noted that TIVADs and tunneled vascular access devices may be inserted for a variety of principal diagnoses, and that adding these 17 diagnoses that are not specific to renal failure would not maintain the clinical coherence with other cases in this subset of cases in MS–DRGs 673, 674, and 675.

We further stated that our clinical advisors also did not support adding ICD–10–CM diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease) to the special logic in MS–DRGs 673, 674, and 675. As discussed previously, code I13.2 is assigned to MDC 05 (Diseases and Disorders of the Circulatory System). Our clinical advisors agreed it would not be appropriate to move this diagnosis into MDC 11 because it would inadvertently cause cases reporting this same MDC 05 diagnosis with circulatory system procedures to be assigned to an unrelated MS–DRG.

Therefore, for the reasons described previously, we did not propose to add the following 18 ICD–10–CM codes to the list of principal diagnosis codes for MS–DRGs 673, 674, and 675 when reported with a procedures code describing the insertion of a TIVAD or a tunneled vascular access device: E10.21, E10.29, E11.21, E11.29, E13.21, E13.29, I13.2, T80.211A, T80.212A, T80.218A, T82.7XXA, T82.818A, T82.828A, T82.838A, T82.848A, T82.858A, T82.868A, and T82.898A.

Comment: Commenters supported our proposal to not add the 18 ICD–10–CM diagnosis codes listed to the special logic in MS–DRGs 673, 674, and 675. One commenter specifically agreed stating these devices may be inserted for a variety of diagnoses, and adding diagnosis codes that are not specific to renal failure would not maintain clinical coherence with other cases in these MS–DRGs.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to not add the following 18 ICD–10–CM codes to the list of principal diagnosis codes for MS–DRGs 673, 674, and 675 when reported with a procedures code describing the insertion of a TIVAD or a tunneled vascular access device: E10.21, E10.29, E11.21, E11.29, E13.21, E13.29, I13.2, T80.211A, T80.212A, T80.218A, T82.7XXA, T82.818A, T82.828A, T82.838A, T82.848A, T82.858A, T82.868A, and T82.898A.

We then reviewed the remaining 11 diagnosis codes submitted by the requestor. Codes T82.41XA, T82.42XA, T82.43XA and T82.49XA describe mechanical complications of vascular dialysis catheters. We stated in the proposed rule that our clinical advisors believe the insertion of TIVADs or tunneled vascular access devices for the purposes of hemodialysis is clearly clinically related to diagnosis codes describing a mechanical complication of a vascular dialysis catheter and that for clinical coherence, these cases should be grouped with the subset of cases that report the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis for renal failure.

As discussed in the proposed rule, codes T82.41XA, T82.42XA, T82.43XA and T82.49XA that describe mechanical complications of vascular dialysis catheters are currently assigned to MDC 05 and would require reassignment to MDC 11 in MS–DRGs 673, 674, and 675 to group with the subset of cases that report the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis for renal failure. We examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from the T82.4- series in MDC 05 and compared this data to cases in MS–DRGs 673, 674 and 675. The following table shows our findings:

MS-DRGs 673, 674 and 675 Compared To Cases Reporting Procedures Describing The Insertion of TIVADs or Tunneled Vascular Access Devices With A Principal Diagnosis Code From T82.4- Series In MDC 05			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 673 - All cases	13,068	11.0	$26,528
Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from T82.4- series in MDC 05 with secondary diagnosis designated as MCC	1,025	4.6	$14,882
MS-DRG 674 - All cases	6,592	7.6	$17,491
Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from T82.4- series in MDC 05 with secondary diagnosis designated as CC	2	6.0	$15,016
MS-DRG 675 - All cases	437	3.4	$12,506
Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from T82.4- series in MDC 05 without secondary diagnosis designated as CC or MCC	1	3.0	$9,317

As shown in the table, there were 13,068 cases in MS–DRG 673 with an average length of stay of 11 days and average costs of $26,528. There were 1,025 cases reporting a principal diagnosis describing a mechanical complication of vascular dialysis catheter, with a secondary diagnosis of MCC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with an average length of stay of 4.6 days and average costs of $14,882. There were 6,592 cases in MS–DRG 674 with an average length of stay of 7.6 days and average costs of $17,491. There were two cases reporting a principal diagnosis describing a mechanical complication of vascular dialysis catheter, with a secondary diagnosis of CC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with an average length of stay of 6 days and average costs of $15,016. There were 437 cases in MS–DRG 675 with an average length of stay of 3.4 days and average costs of $12,506. There was one case reporting a principal diagnosis describing a mechanical complication of vascular dialysis catheter, without a secondary diagnosis of CC or MCC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with a length of stay of 3 days and costs of $9,317. Our clinical advisors noted that the average length of stay and average costs of cases reporting a diagnosis describing a mechanical complication of a vascular dialysis catheter and the insertion of a TIVAD or a tunneled vascular access device are lower than for all cases in MS–DRGs 673, 674, and 675, respectively.

For the reasons discussed, we stated in the proposed rule that our clinical advisors believe that it is clinically appropriate for the four ICD–10–CM diagnosis codes describing a mechanical complication of a vascular dialysis catheter to group to the subset of GROUPER logic that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis. Therefore, we proposed to reassign ICD–10–CM diagnosis codes T82.41XA, T82.42XA, T82.43XA, and T82.49XA from MDC 05 in MS–DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) assigned to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) and 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively).

Comment: One commenter questioned the rationale as to the extent totally implantable vascular access devices (TIVADs) are considered ''kidney and urinary tract procedures'' when placed to address a condition assigned to MDC 05.

Response: We appreciate the commenters' concern.

As discussed in the proposed rule, the procedure code for the insertion of totally implantable vascular access devices was originally added to the GROUPER logic of DRG 315 (Other Kidney and Urinary Tract O.R. Procedures), the predecessor DRG of MS–DRGs 673, 674, and 675, when combined with principal diagnoses specifically describing renal failure, recognizing that these devices are inserted as an inpatient procedure for the purposes of hemodialysis. Our clinical advisors believe the four ICD–10–CM diagnosis codes describing a mechanical complication of a vascular dialysis catheter are clearly clinically related to diagnosis codes that describe renal failure because the complicated vascular dialysis catheter described by these diagnosis codes would not be in place if hemodialysis was not indicated. Therefore, our clinical advisors believe that it is clinically appropriate for the four ICD–10–CM diagnosis codes describing a mechanical complication of a vascular dialysis catheter to group to

the subset of GROUPER logic that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis.

Comment: Other commenters supported the reassignment of diagnosis codes describing a mechanical complication of a vascular dialysis catheter to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) and 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively) in MDC 11.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to reassign ICD–10–CM diagnosis codes T82.41XA, T82.42XA, T82.43XA, and T82.49XA from MDC 05 in MS–DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) assigned to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) and 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively) under the ICD–10 MS–DRGs Version 38, effective October 1, 2020.

In reviewing ICD–10–CM codes E10.22, E11.22, and E13.22 describing diabetes mellitus with diabetic chronic kidney disease, we noted that related ICD–10–CM diagnosis code E09.22 (Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease) is also not included in the current list of diagnosis codes included in the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices, and therefore we included E09.22 in our review. ICD–10–CM assumes a causal relationship between diabetes mellitus and chronic kidney disease. According to the ICD–10–CM Official Guidelines for Coding and Reporting, the word ''with'' or ''in'' should be interpreted to mean ''associated with'' or ''due to'' when it appears in a code title, the Alphabetic Index (either under a main term or subterm), or an instructional note in the Tabular List, meaning these conditions should be coded as related even in the absence of provider documentation explicitly linking them, unless the documentation clearly states the conditions are unrelated. To code diabetic chronic kidney disease in ICD–10–CM, instructional notes direct to ''code first any associated diabetic chronic kidney disease'' (that is, E09.22, E10.22, E11.22, and E13.22) with a second code from subcategory of N18 listed after the diabetes code to specify the stage of chronic kidney disease. Recognizing that coding guidelines instruct to code E09.22, E10.22, E11.22, and E13.22 before codes that specify the stage of chronic kidney disease, our clinical advisors recommended adding diabetic codes E09.22, E10.22, E11.22, and E13.22 when reported with a secondary diagnosis of either N18.5 Chronic kidney disease, stage 5) or N18.6 (End stage renal disease) to the special logic in MS–DRGs 673, 674, and 675 since these diagnosis code combinations describe an indication that could require the insertion of a totally implantable vascular access device or a tunneled vascular access device to allow access to the patient's blood for hemodialysis purposes.

ICD–10–CM codes T86.11, T86.12, T86.13, and T86.19 describe complications of kidney transplant and are currently assigned to MDC 11. We stated our clinical advisors believe these diagnoses are also indications for hemodialysis and these cases represent a distinct, recognizable clinical group similar to those cases in the subset of cases assigned to the special logic in MS–DRGs 673, 674, and 675 when reported with procedure codes describing the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis.

To summarize, we proposed to add ICD–10–CM codes E09.22, E10.22, E11.22, and E13.22, when reported with a secondary diagnosis of N18.5 or N18.6, to the list of principal diagnosis codes in the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis. We also proposed to add ICD–10–CM codes T86.11, T86.12, T86.13, and T86.19 to the list of principal diagnosis codes in this subset of GROUPER logic in MS–DRGs 673, 674, and 675.

Comment: Commenters supported our proposal to add ICD–10–CM codes E09.22, E10.22, E11.22, and E13.22, when reported with a secondary diagnosis of N18.5 or N18.6, to the list of principal diagnosis codes in the subset of GROUPER logic in MS–DRGs 673, 674, and 675. The commenters stated they agreed that these diagnosis code combinations describe an indication that could require the insertion of a totally implantable vascular access device or a tunneled vascular access device for hemodialysis purposes. Commenters also supported the addition of ICD–10–CM codes for complications of kidney transplant to the list of principal diagnosis codes in the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add ICD–10–CM codes E09.22, E10.22, E11.22, and E13.22, when reported with a secondary diagnosis of N18.5 or N18.6, to the list of principal diagnosis codes in the subset of GROUPER logic in MS–DRGs 673, 674, and 675. We are also finalizing our proposal to add ICD–10–CM codes T86.11, T86.12, T86.13, and T86.19 to the list of principal diagnosis codes in this subset of GROUPER logic in MS–DRGs 673, 674, and 675.

Lastly, we reviewed the current list of 20 MDC 11 diagnoses assigned to the special logic in MS–DRGs 673, 674, and 675 when reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices. The list of MDC 11 diagnosis codes currently included in the special logic of MS–DRGs 673, 674, and 675 are found in the following table:

ICD-10-CM Code	Code Description
E88.3	Tumor lysis syndrome
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
N17.0	Acute kidney failure with tubular necrosis
N17.1	Acute kidney failure with acute cortical necrosis
N17.2	Acute kidney failure with medullary necrosis
N17.8	Other acute kidney failure
N17.9	Acute kidney failure, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified
N19	Unspecified kidney failure
R34	Anuria and oliguria
T79.5XXA	Traumatic anuria, initial encounter

As stated in the proposed rule, our clinical advisors pointed out that ICD–10–CM codes I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, and N18.9 do not describe renal failure and they do not describe indications that would generally require the insertion of totally implantable vascular access devices or tunneled vascular access devices for the purposes of hemodialysis. Our advisors noted hemodialysis replicates the function of the kidneys. In cases of acute kidney failure and anuria, hemodialysis is indicated to prevent urea and other waste material from building up in the blood until the kidneys return to normal function. A diagnosis of chronic kidney disease stages 1 through 4, however, means the kidneys still have the ability to filter waste and extra fluid out of the blood. Dialysis is not often initiated in chronic kidney disease until the chronic kidney disease progresses to stage 5 or ESRD, which is defined as when kidney function drops to 15 percent or less. Our clinical advisors stated that these seven codes do not describe indications requiring the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis and recommended these codes be removed from the special logic in MS–DRGs 673, 674, and 675.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 673, 674, and 675 for this subset of cases to determine if there were any cases that reported one of the seven ICD–10–CM codes in the special logic of MS–DRGs 673, 674, and 675 that do not necessarily describe indications requiring the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis, the frequency with which they were reported and the relative resource use as compared with all cases assigned to the special logic in MS–DRGs 673, 674, and 675. The following table shows our findings:

MS-DRG 673, 674 and 675				
MS-DRG	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
673	MDC 11 diagnosis with procedure code describing insertion of TIVAD/tunneled VAD	7,391	12.1	$28,273
	Cases with principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with procedure code describing insertion of TIVAD/tunneled VAD	34	14.2	$27,844
674	MDC 11 diagnosis with procedure code describing insertion of TIVAD/tunneled VAD	3,055	7.8	$17,107
	Cases with principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with procedure code describing insertion of TIVAD/tunneled VAD	30	7.2	$11,227
675	MDC 11 diagnosis with procedure code describing insertion of TIVAD/tunneled VAD	58	6.1	$12,582
	Cases with principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, of N18.9 with procedure code describing insertion of TIVAD/tunneled VAD	1	4	$6,549

As shown by the table, for MS–DRG 673, we identified a total of 7,391 cases assigned to the special logic within this MS–DRG with an average length of stay of 12.1 days and average costs of $28,273. Of these 7,391 cases in the subset of MS–DRG 673, there were 34 cases describing insertion of a TIVAD or tunneled vascular access device with a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with an average length of stay of 14.2 days and average costs of $27,844. For MS–DRG 674, we identified a total of 3,055 cases assigned to the special logic within this MS–DRG with an average length of stay of 7.8 days and average costs of $17,107. Of these 3,055 cases in the subset of MS–DRG 674, there were 30 cases describing insertion of a TIVAD or tunneled vascular access device with a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with an average length of stay of 7.2 days and average costs of $11,227. For MS–DRG 675, we identified a total of 58 cases assigned to the special logic within this MS–DRG with an average length of stay of 6.1 days and average costs of $12,582. Of these 58 cases in the subset of MS–DRG 675, there was one case describing insertion of a TIVAD or tunneled vascular access device with a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with a length of stay of 4 days and costs of $6,549. Overall, for MS–DRGs 673, 674 and 675, there were a relatively small number of cases reporting a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 and a procedure code describing the insertion of a TIVAD or tunneled vascular access device demonstrating that these conditions are not typically addressed by insertion of these devices.

As stated previously, TIVADs and tunneled vascular access devices may be inserted for a variety of principal diagnoses. We stated in the proposed rule that our clinical advisors believe that continuing to include these seven diagnoses that are not specific to renal failure or that do not otherwise describe indications requiring the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis would not maintain clinical coherence with other cases in this subset of cases in MS–DRGs 673, 674, and 675. Therefore, for the reasons stated, we proposed to remove ICD–10–CM codes I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, and N18.9 from the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis.

Comment: One commenter expressed concerns about the proposal and did not fully agree with this change. This commenter described a scenario in which a patient with stage 3 chronic kidney disease develops acute kidney failure and has totally implantable vascular access device inserted for the purpose of hemodialysis during an inpatient hospitalization. The commenter questioned if this scenario would qualify for the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis.

Response: We appreciate the commenter's concern.

As discussed in the proposed rule, ICD–10–CM diagnosis codes N17.0,

N17.1 N17.2, N17.8 and N17.9 which describe acute kidney failure are currently included in the special logic of MS–DRGs 673, 674, and 675. These codes were not listed in the seven codes proposed to be removed. In the hypothetical scenario described by the commenter, the case would qualify for the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as long as the diagnosis of acute kidney failure met the definition of principal diagnosis. We encourage the commenter to review the Official ICD–10–CM Coding Guidelines, which can be found on the CDC website at: *http://www.cdc.gov/nchs/icd/icd10.htm*.

Comment: Other commenters supported our proposal and stated they agreed that the seven ICD–10–CM codes that do not describe renal failure or indications that would generally require the insertion of totally implantable vascular access devices for the purpose of hemodialysis should be removed from the special logic in MS–DRGs 673, 674, and 675.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to remove ICD–10–CM codes I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, and N18.9 from the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis under the ICD–10 MS–DRGs Version 38, effective October 1, 2020.

9. MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms): Inferior Vena Cava Filter Procedures

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32524), we received a request to review the GROUPER logic in MDC 17. The requester stated that cases reporting the introduction of a high dose chemotherapy agent, or reporting a chemotherapy principal diagnosis with a secondary diagnosis describing acute leukemia, are assigned to medical MS–DRGs 837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC), MS–DRG 838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent), and MS–DRG 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC). However, when procedure codes describing the placement of an inferior vena cava (IVC) filter, namely 06H03DZ (Insertion of intraluminal device into inferior vena cava, percutaneous approach), are also reported with the same codes describing the introduction of a high dose chemotherapy agent or report a chemotherapy principal diagnosis with a secondary diagnosis describing acute leukemia, the cases are assigned to surgical MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with and without CC/MCC, respectively). According to the requestor, the additional resources used by the hospital to place an IVC filter should not result in assignment to lower-weighted MS–DRGs.

As stated in the proposed rule, the ICD–10–PCS codes that describe the insertion of an infusion device or the insertion of an intraluminal device into the inferior vena cava are listed in the following table.

ICD-10-PCS Code	Code Description
06H003T	Insertion of infusion device, via umbilical vein, into inferior vena cava, open approach
06H003Z	Insertion of infusion device, into inferior vena cava, open approach
06H00DZ	Insertion of intraluminal device, into inferior vena cava, open approach
06H033T	Insertion of infusion device, via umbilical vein, into inferior vena cava, percutaneous approach
06H033Z	Insertion of infusion device, into inferior vena cava, percutaneous approach
06H03DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous approach
06H043Z	Insertion of infusion device, into inferior vena cava, percutaneous endoscopic approach
06H04DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous endoscopic approach

We stated our analysis of this grouping issue confirmed that, when procedure code 06H03DZ (Insertion of intraluminal device into inferior vena cava, percutaneous approach) is reported with a procedure code describing the introduction of a high dose chemotherapy agent, or when it is reported with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia, these cases group to surgical MS–DRGs 829 and 830. ICD–10–PCS procedure code 06H03DZ identifies the placement of an IVC filter and is designated as an extensive O.R. procedure for purposes of MS–DRG assignment. We then examined the GROUPER logic for medical MS–DRGs 837, 838 and 839. The GROUPER logic for MS–DRGs 837, 838, and 839 is defined by a principal diagnosis of chemotherapy identified with ICD–10–CM diagnosis codes Z08 (Encounter for follow-up examination after completed treatment for malignant neoplasm), Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.112 (Encounter for antineoplastic immunotherapy) along with a secondary diagnosis of acute leukemia or a procedure code for the introduction of a high dose

chemotherapy agent as reflected in the logic table:

Secondary Diagnosis of Acute Leukemia	High Dose Chemotherapy Agent	MCC	CC	MS-DRG
Yes		Yes	n/a	837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC)
No	Yes	Yes	n/a	837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC)
Yes	No	No	Yes	838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent)
No	Yes	No	n/a	838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent)
Yes	No	No	No	839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC)

We refer the reader to the ICD–10 MS-DRG Version 37 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the listed MS–DRGs.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRGs 829 and 830 and for cases reporting the insertion of an IVC filter (procedure codes 06H00DZ, 06H03DZ, and 06H04DZ) with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
829	All cases	1,697	9.2	$24,188
	Cases reporting insertion of an IVC filter procedure code with the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia	18	25.6	$83,861
830	All cases	311	2.9	$10,885

As shown in the table, there were a total of 1,697 cases with an average length of stay of 9.2 days and average costs of $24,188 in MS–DRG 829. Of those 1,697 cases, there were 18 cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia with an average length of stay of 25.6 days and average costs of $83,861. We noted that there were no cases reporting procedure codes 06H00DZ or 06H04DZ. For MS–DRG 830, there were a total of 311 cases with an average length of stay of 2.9 days and average costs of $10,885. We found zero cases in MS–DRG 830 reporting a procedure code for the insertion of an IVC filter with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia. Based on the claims data, the cases reporting procedure code 06H03DZ with a

procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia have higher average costs ($83,861 versus $24,188) and a longer average length of stay (25.6 days versus 9.2 days) than all the cases in MS–DRG 829.

We also reviewed the claims data for MS–DRGs 837, 838, and 839. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
837 - All cases	1,776	17	$40,667
838 - All cases	1,172	7.3	$16,594
839 - All cases	810	5	$10,994

As shown in the table, there were a total of 1,776 cases with an average length of stay of 17 days and average costs of $40,667 in MS–DRG 837. There were a total of 1,172 cases with an average length of stay of 7.3 days and average costs of $16,594 in MS–DRG 838. There were a total of 810 cases with an average length of stay of 5 days and average costs of $10,994 in MS–DRG 839. Based on the claims data, the cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia again have higher average costs ($83,861 versus $40,667, $16,594, and $10,994 respectively) and a longer average length of stay (25.6 days versus 17 days, 7.3 days and 5 days, respectively) than all the cases in MS–DRG 837, 838, and 839. We stated our clinical advisors reviewed the claims data and noted there were only a small number of cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia, and believe there may have been other factors contributing to the higher costs for these cases. Our clinical advisors stated the procedure to insert an IVC filter is not surgical in nature and recommended further analysis.

We performed further analysis on the other ICD–10–PCS codes describing the insertion of a device into the inferior vena cava to identify if they have a similar extensive O.R. designations and noted inconsistencies among the O.R. and non-O.R. designations. In Version 37 of the ICD–10 MS–DRGs, ICD–10–PCS procedure codes 06H003T, 06H003Z, 06H033T, 06H033Z, and 06H043Z identify the insertion of an infusion device into the inferior vena cava with various approaches and are classified as Non-O.R. procedures. ICD–10–PCS procedure codes 06H00DZ, 06H03DZ, and 06H04DZ identify the insertion of an intraluminal device into the inferior vena cava (IVC filter procedure) with various approaches and are classified as extensive O.R. procedures. We stated that our clinical advisors indicated that codes 06H00DZ, 06H03DZ, and 06H04DZ describing the insertion of an intraluminal device into the inferior vena cava do not require the resources of an operating room, that the procedure to insert an IVC filter is not surgical in nature and that these procedures are comparable to the related ICD–10–PCS procedure codes that describe the insertion of infusion devices into the inferior vena cava that are currently designated as Non-O.R. procedures. We stated our clinical advisors believe that, given the similarity in factors such as complexity, resource utilization, and lack of a requirement for anesthesia administration between all procedures describing insertion of a device into the inferior vena cava, it would be more appropriate to designate these three ICD–10–PCS codes describing the insertion of an intraluminal device into the inferior vena cava as Non-O.R. procedures. Therefore, we proposed to remove ICD–10–PCS procedure codes 06H00DZ, 06H03DZ, and 06H04DZ from the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

Comment: A few commenters supported CMS' proposal and agreed ICD–10–PCS procedure codes 06H00DZ, 06H03DZ, and 06H04DZ describing the insertion of an intraluminal device into the inferior vena cava should be designated as non-O.R. procedures since these procedures are not surgical in nature, and related ICD–10–PCS codes are currently designated as non-O.R. procedures.

Response: We appreciate the commenters' support.

Comment: A commenter stated that they recommend that CMS remove code Z08 from the GROUPER logic for MS–DRGs 837, 838, and 839. The commenter stated that ICD–10–CM code Z08 identifies a follow-up visit after completed treatment for a malignant neoplasm which implies that the condition has been fully treated and no longer exists. Therefore, ICD–10–CM code Z08 does not describe an admission for chemotherapy. This commenter also noted that code Z08 is on the Unacceptable Principal diagnosis edit code list.

Response: We appreciate the commenters' concern.

The GROUPER logic assignment for each diagnosis code as a principal diagnosis is for grouping purposes only. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41227), because the diagnoses are codes listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS–DRG Definitions Manual, it may appear to indicate that these codes are to be reported as a principal diagnosis for assignment to these MS–DRGs. However, the Definitions Manual display of the GROUPER logic assignment for each diagnosis code does not correspond to coding guidelines for reporting the principal diagnosis. The MS–DRG logic must specifically require a condition to group based on whether it is reported as a principal diagnosis or a secondary diagnosis, and consider any procedures that are reported, in addition to consideration of the patient's age, sex and discharge status in order to affect the MS–DRG assignment. In other words, cases will group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. It is the Medicare Code Editor (MCE)

and other payer-specific edits that identify inconsistencies in the coding guidelines or coverage policies. The MCE is designed to identify cases that require further review before classification into an MS–DRG. These data integrity edits address issues such as data validity, coding rules, and coverage policies. Since the inception of the IPPS, the data editing function has been a separate and independent step in the process of determining a DRG assignment. The separation of the MS–DRG grouping and data editing functions allows the MS–DRG GROUPER to remain stable even though coding rules and coverage policies may change during the fiscal year.

Comment: Other commenters opposed CMS' proposal. A commenter stated the insertion of vena cava filters requires the use of specialized interventional radiology suites and in other hospitals without such specialized suites, the procedure may be performed in a multipurpose operating room. A few commenters stated that that the insertion of an inferior vena cava filter is not comparable to the insertion of an infusion device and that while it may be true that in some hospitals the procedure may be done at bedside similar to the insertion of infusion devices, this is not universally true and facilities incur significant costs beyond those for infusion devices to compensate for the costly implanted devices, specialized procedure rooms, equipment, and skill. A commenter stated that they believe that this proposed change will result in insufficient reimbursement for the resources utilized in delivering care to these patients. One commenter specifically noted that the costs of vena cava filters are higher than infusion catheters because filters can easily add over $4,000 to the cost of the procedure. Another commenter stated all open and laparoscopic vascular procedures should always be designated as O.R. procedures strictly because of the approach.

Response: We appreciate the commenters' feedback and concern.

With regard to the comments about the implications for reimbursement, we note that the goals of changing the designation of procedures from non-O.R. to O.R., or vice versa, are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system. Therefore, decisions to change an O.R. designation are based on whether such a change would accomplish those goals and not whether the change in designation would impact the payment in a particular direction.

Our clinical advisors reviewed the commenters' concerns and continue to support changing the O.R. designation of procedures describing insertion of an intraluminal device into the inferior vena cava performed via a percutaneous approach for consistency with the other procedure codes describing the insertion of a device into the inferior vena cava that are currently designated as non-O.R procedures because, as commenters noted in their own comments, inferior vena cava filters are most often placed in Interventional Radiology suites. The resources involved in furnishing these procedures are consistent with non-O.R. procedures and our clinical advisors noted it is not uncommon for anesthesia to be used in the radiology suite. Our clinical advisors also disagree with the assertion that these procedures are dissimilar to procedures describing the insertion of infusion devices into the inferior vena cava and believe that these procedures involve similar technical complexity.

Our clinical advisors do, however, concur with the commenters that while the procedure to insert an IVC filter is not surgical in nature, procedures describing the insertion of an intraluminal device into the inferior vena cava performed via an open or a percutaneous endoscopic approach could require greater resources than a procedure describing insertion of an intraluminal device into the inferior vena cava performed via a percutaneous approach. As such, we believe that at this time it would be appropriate to take additional time to further examine the relevant clinical factors and similarities in resource consumption between procedures describing the insertion of an intraluminal device into the inferior vena cava performed via an open or a percutaneous endoscopic approach. As discussed in section II.E.11. of the preamble of this final rule, we are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We continue to develop our process and methodology, and will provide more detail in future rulemaking.

Therefore, after consideration of the public comments we received, and for the reasons stated above, under the ICD–10 MS–DRGs Version 38, effective October 1, 2020, we are (1) finalizing our proposal to change the designation of ICD–10–PCS procedure code 06H03DZ from O.R. procedure to non-O.R. procedure and (2) maintaining the O.R. designation of procedure codes 06H00DZ and 06H04DZ. Accordingly, procedure codes 06H00DZ and 06H04DZ will continue to impact MS–DRG assignment.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine. We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS DRGs to which the procedure codes are assigned.

Based on the results of our review of the claims data from the September 2019 update of the FY 2019 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we proposed to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

a. Horseshoe Abscess With Drainage

As discussed in the proposed rule, we received a request to reassign cases reporting a principal diagnosis of a horseshoe abscess with a procedure involving open drainage of perineum subcutaneous tissue and fascia from MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06. ICD–10–CM diagnosis code K61.31 (Horseshoe abscess) is used to report a horseshoe abscess and is currently assigned to MDC 06 (Diseases and Disorders of the Digestive System). A horseshoe abscess is a specific type of ischiorectal abscess caused by an abscessed anal gland located in the posterior midline of the anal canal with suppuration found in the ischiorectal fossae. ICD–10–PCS procedure code 0J9B0ZZ (Drainage of perineum subcutaneous tissue and fascia, open approach) may be reported to describe drainage of an abscess in the ischiorectal space and is currently assigned to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) and MDC 24 (Multiple Significant Trauma).

We stated in the proposed rule that our analysis of this grouping issue confirmed when a horseshoe abscess is reported as a principal diagnosis with ICD–10–PCS procedure code 0J9B0ZZ, these cases group to MS–DRGs 987, 988, and 989. As previously noted, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We first examined the claims data to identify cases reporting procedure code 0J9B0ZZ with a principal diagnosis of K61.31 that are currently grouping to MS–DRGs 987, 988, and 989. Our findings are shown in this table:

MS-DRGs 987 – 989: Cases Reporting Procedure Describing Open Drainage Of Perineum Subcutaneous Tissue And Fascia with Principal Diagnosis K61.31

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
987	1	5	$10,966
988	0	0	$0
989	2	1.5	$3,596

As previously noted, the requester asked that we reassign these cases to MS–DRGs 356, 357, and 358. We therefore examined the data for all cases in MS–DRGs 356, 357, and 358. Our findings are shown in this table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
356 – All cases	7,525	10.4	$30,071
357 – All cases	5,759	5.9	$16,452
358 – All cases	1,191	3.4	$10,031

We stated while our clinical advisors noted that the average length of stay and average costs of cases in MS–DRGs 356, 357, and 358 are higher than the average length of stay and average costs for the small subset of cases reporting procedure code 0J9B0ZZ and a principal diagnosis code of K61.31 in MS–DRGs 987, 988, and 989, they believe that the procedure is clearly clinically related to the principal diagnosis and is a logical accompaniment of the diagnosis. Therefore, they believe it is clinically appropriate for the procedure to group to the same MS–DRGs as the principal diagnosis.

Therefore, we proposed to add ICD–10–PCS procedure code 0J9B0ZZ to MDC 06 in MS–DRGs 356, 357, and 358. Under this proposal, cases reporting procedure code 0J9B0ZZ in conjunction with a principal diagnosis from MDC 06, such as diagnosis code K61.31, would group to MS–DRGs 356, 357, and 358.

Comment: Commenters supported our proposal to add ICD–10–PCS procedure code 0J9B0ZZ to MDC 06 in MS–DRGs 356, 357, and 358.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add ICD–10–PCS procedure code 0J9B0ZZ to MDC 06 in MS–DRGs 356, 357, and 358.

b. Chest Wall Deformity With Supplementation

We received a request to reassign cases reporting a principal diagnosis of acquired deformity of chest and rib with a procedure involving the placement of a biological or synthetic material that supports or strengthens the body part from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 08.

As discussed in the proposed rule, ICD–10–CM diagnosis code M95.4 (Acquired deformity of chest and rib) is used to report this condition and is currently assigned to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). ICD–10–PCS procedure codes 0WU807Z (Supplement chest wall with autologous tissue substitute, open approach), 0WU80JZ (Supplement chest wall with synthetic substitute, open approach) and 0WU80KZ (Supplement chest wall with nonautologous tissue substitute, open approach) may be reported to describe procedures to supplement or reinforce the chest wall with biologic or synthetic material. ICD–10–PCS procedure codes 0WU807Z and 0WU80KZ are currently assigned to MDC 04 (Diseases and Disorders of the Respiratory System). We noted that ICD–10–PCS procedure code 0WU80JZ is already assigned to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) as well as MDC 04 (Diseases and Disorders of the Respiratory System), so these cases already group to MS–DRGs 515, 516, and 517 when reported with a principal diagnosis of ICD–10–CM diagnosis code M95.4.

We stated in the proposed rule that our analysis of this grouping issue confirmed that when diagnosis code M95.4 is reported as a principal diagnosis with ICD–10–PCS procedure codes 0WU807Z or 0WU80KZ, these cases group to MS–DRGs 981, 982, and 983. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases reporting procedure codes 0WU807Z or 0WU80KZ with principal diagnosis code M95.4 that are currently grouping to MS–DRGs 981, 982, and 983. Our analysis showed one case reporting a principal diagnosis of code M95.4 with procedure code 0WU807Z, with a length of stay of 2.0 days and average costs of $11,594 in MS–DRG 983. We found zero cases in MS–DRGs 981 and 982 reporting procedure codes 0WU807Z or 0WU80KZ and a principal diagnosis of M95.4.

We also examined the data for cases in MS–DRGs 515, 516, and 517, and our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
515 – All cases	4,655	8.2	$22,176
516 – All cases	13,308	4.6	$14,225
517 – All cases	11,992	2.6	$10,318

While there was only one case reporting procedure codes 0WU807Z or 0WU80KZ with principal diagnosis M95.4 in MS–DRGs 981, 982, and 983, we stated our clinical advisors reviewed this request and believe that the cases involving procedures of chest wall supplementation with a principal diagnosis of acquired deformity of chest and rib represent a distinct, recognizable clinical group similar to those cases in MS–DRGs 515, 516, and 517, and that procedures reporting 0WU80JZ and 0WU80KZ are clearly related to the principal diagnosis code. They believe that it is clinically appropriate for the three ICD–10–PCS codes describing procedures to supplement or reinforce the chest wall with biologic or synthetic material to group to the same MS–DRGs as the principal diagnoses.

Therefore, we proposed to add ICD–10–PCS procedure codes 0WU807Z and 0WU80KZ to MDC 08 in MS–DRGs 515, 516, and 517. Under this proposal, cases reporting procedure codes 0WU807Z or 0WU80KZ in conjunction with a principal diagnosis code from MDC 08 would group to MS–DRGs 515, 516, and 517.

Comments: Commenters supported the proposal to add ICD–10–PCS procedure codes 0WU807Z and 0WU80KZ to MDC 08 in MS–DRGs 515, 516, and 517. The commenters stated that the proposal was reasonable, given the ICD–10–CM code and the information provided. One commenter specifically stated this reassignment would allow procedures describing chest wall supplementation to be assigned to the appropriate MS–DRG when reported with the principal diagnosis of acquired deformity of chest and rib instead of one of the unrelated operating room procedure MS–DRGs. Another commenter stated this would improve clinical consistency since one of the codes describing these procedures is already assigned to MDC 08.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 0WU807Z and 0WU80KZ to MDC 08 in MS–DRGs 515, 516, and 517.

c. Hepatic Malignancy With Hepatic Artery Embolization

As discussed in the proposed rule, we received a request to reassign cases for hepatic malignancy when reported with procedures involving the embolization of a hepatic artery from MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 423, 424, and 425 (Other Hepatobiliary or Pancreas Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 08.

We stated in the proposed rule that ICD–10–PCS procedure code 04V33DZ (Restriction of hepatic artery with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to narrow or partially occlude a hepatic artery with an intraluminal device and is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System). ICD–10–PCS procedure code 04L33DZ (Occlusion of hepatic artery with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to completely close off a hepatic artery with an intraluminal device and is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System) and MDC 06 (Diseases and Disorders of the Digestive System).

The requestor did not provide an ICD–10–CM diagnosis code in its request so we reviewed ICD–10–CM diagnosis codes in the C00 through D49 code range to identify conditions that describe hepatic malignancies. We

identified the following fourteen ICD–10–CM diagnosis codes, all currently assigned to MDC 07 (Diseases and Disorders of the Hepatobiliary System & Pancreas):

ICD-10-CM Code	Code Description
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C7B.02	Secondary carcinoid tumors of liver
D01.5	Carcinoma in situ of liver, gallbladder and bile ducts

Our analysis of this grouping issue confirmed that, when one of the fourteen hepatic malignancy ICD–10–CM diagnosis codes previously listed is reported as a principal diagnosis with ICD–10–PCS procedure code 04L33DZ, these cases group to MS–DRGs 987, 988, and 989. However, we noted that when one of these fourteen hepatic malignancy ICD–10–CM diagnosis codes is reported as a principal diagnosis with ICD–10–PCS procedure code 04V33DZ, these cases currently group to MS DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

To understand the resource use for the subset of cases reporting procedure code 04V33DZ with a principal diagnosis of hepatic malignancy that are currently grouping to MS–DRGs 981, 982, and 983, we examined claims data for the average length of stay and average costs for these cases. Our findings are shown in the following table:

MS-DRGs 981 – 983: Cases Reporting Procedure Describing Percutaneous Restriction Of Hepatic Artery With Intraluminal Device with Principal Diagnosis Of Hepatic Malignancy			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981	17	5.4	$22,447
982	9	6.0	$23,279
983	3	1.3	$10,697

We then examined the claims data to identify cases reporting procedure code 04L33DZ reported with a principal diagnosis of hepatic malignancy that are currently grouping to MS–DRGs 987, 987, and 989. Our findings are shown in the following table:

MS-DRGs 987 – 989: Cases Reporting Procedures Describing Percutaneous Occlusion Of Hepatic Artery With Intraluminal Device with Principal Diagnosis Of Hepatic Malignancy			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
987	107	9.0	$30,179
988	70	4.3	$18,079
989	41	1.7	$10,635

We also examined the data for cases in MS–DRGs 423, 424, and 425, and our findings are shown in the following table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
423 – All cases	825	12.2	$29,944
424 – All cases	362	6.8	$16,588
25 – All cases	59	3.5	$11,158

While the average lengths of stay of cases in MS–DRGs 423, 424, and 425 are longer than the average lengths of stay for the subset of cases reporting procedure codes 04V33DZ or 04L33DZ and a principal diagnosis of hepatic malignancy, the average costs of these same cases are generally similar. We stated our clinical advisors also believe that these procedures are clearly related to the principal diagnoses, as they are an appropriate treatment for a number of hepatobiliary diagnoses, including cancer and it is clinically appropriate for the procedures to group to the same MDC as the principal diagnoses.

Therefore, we proposed to add ICD–10–PCS procedure codes 04V33DZ and 04L33DZ to MDC 07 in MS–DRGs 423, 424 and 425. Under this proposal, cases reporting procedure codes 04V33DZ or 04L33DZ in conjunction with a principal diagnosis code for a hepatic malignancy from MDC 07 would group to MS–DRGs 423, 424 and 425.

Comments: Commenters supported our proposal to add ICD–10–PCS procedure codes 04V33DZ and 04L33DZ to MDC 07 in MS–DRGs 423, 424 and 425.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add ICD–10–PCS procedure codes 04V33DZ and 04L33DZ to MDC 07 in MS–DRGs 423, 424 and 425.

d. Hemoptysis With Percutaneous Artery Embolization

We received a request to reassign cases for hemoptysis when reported with a procedure describing percutaneous embolization of an upper artery with an intraluminal device from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04. As discussed in the proposed rule, hemoptysis is the expectoration of blood from some part of the respiratory tract. ICD–10–CM diagnosis code R04.2 (Hemoptysis) is used to report this condition and is currently assigned to MDC 04 (Diseases and Disorders of the Respiratory System). ICD–10–PCS procedure code 03LY3DZ (Occlusion of upper artery with intraluminal device, percutaneous approach) may be reported to describe percutaneous embolization of an upper artery with an intraluminal device and is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System), MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) and MDC 24 (Multiple Significant Trauma).

Our analysis of this grouping issue confirmed that when a procedure describing percutaneous embolization of an upper artery with an intraluminal device (such as ICD–10–PCS procedure code 03LY3DZ) is reported with a principal diagnosis from MDC 04, such as R04.2, these cases group to MS–DRGs 981, 982, and 983. We stated during our review of this issue, we also examined claims data for similar procedures 03LY0DZ (Occlusion of upper artery with intraluminal device, open approach) and 03LY4DZ (Occlusion of upper artery with intraluminal device, percutaneous endoscopic approach) and noted the same pattern. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases reporting procedure codes 03LY0DZ, 03LY3DZ or 03LY4DZ with a principal diagnosis from MDC 04 that are currently grouping to MS–DRGs 981, 982, and 983. Our findings are shown in this table:

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Percutaneous Embolization Of An Upper Artery with an Intraluminal Device with a Principal Diagnosis in MDC 04			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
981	135	9.3	$32,912
982	69	5.3	$21,235
983	4	2.5	$30,010

As indicated earlier, the requestor suggested that we move ICD–10–PCS procedure code 03LY3DZ to MS–DRGs 163, 164, and 165. We stated, however, our clinical advisors believe that, within MDC 04, procedure codes describing percutaneous embolization of an upper artery with an intraluminal device are more clinically aligned with the procedure codes assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively), as these procedures would not be considered major chest procedures. Therefore, we examined claims data to identify the average length of stay and average costs for cases assigned to MS–DRGs 166, 167 and 168. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
166	11,380	10.3	$26,702
167	6,575	4.9	$13,556
168	2,189	2.6	$10,149

While our clinical advisors noted that the average costs of cases in MS–DRGs 166, 167, and 168 are lower than the average costs for the subset of cases reporting procedure codes 03LY0DZ, 03LY3DZ or 03LY4DZ and a principal diagnosis code from MDC 04, they believe that these procedures are clearly related to the principal diagnoses as these procedures are appropriate for certain respiratory tract diagnoses. We stated that therefore, it is clinically appropriate for the procedures to group to the same MDC as the principal diagnoses.

Therefore, we proposed to add ICD–10–PCS procedure codes 03LY0DZ, 03LY3DZ and 03LY4DZ to MDC 04 in MS–DRGs 166, 167, and 168. Under this proposal, cases reporting procedure codes 03LY0DZ, 03LY3DZ or 03LY4DZ in conjunction with a principal diagnosis code from MDC 04 such as hemoptysis (R04.2) would group to MS–DRGs 166, 167, and 168.

Comment: A few commenters supported our proposal.

Response: We appreciate the commenters' support.

Comment: A commenter stated that ICD–10–PCS does not have procedure codes with a root operation of control in association with these upper arteries and there are times when an embolization procedure to control acute bleeding manifested as hemoptysis is necessary. This commenter also stated that the correct ICD–10–PCS root operation involving an intervention to address current acute or postprocedural bleeding or to prevent future bleeding is control involving the organ that is bleeding.

Response: We appreciate the commenter raising its concerns.

While we agree that the ICD–10–PCS Official Guidelines for Coding and Reporting define the root operation ''control'' as ''stopping or attempting to stop, postprocedural or other acute bleeding'', the guidelines also state that if a more definitive root operation is required to stop the bleeding then the more definitive root operation is coded instead of ''control''. That is, when embolization is performed to stop acute postprocedural or other acute bleeding of a tubular body part, the more definitive root operations that should be coded in those instances are restriction (if the intent is to partially close) or occlusion (if the intent is to completely occlude) the tubular body part, and not the root operation ''control''. We encourage this commenter to review the posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs.html*.

Comment: Another commenter disagreed with our proposal and stated hemoptysis could be due to other non-respiratory reasons and believed these procedures should be assigned to a ''circulatory'' over a ''respiratory'' DRG if the source of bleeding is not known and a non-respiratory artery or circulatory vessel is occluded to stop the bleeding.

Response: We disagree with the commenter that hemoptysis can be due to other non-respiratory reasons and note that the term ''hemoptysis'' specifically refers to the expectoration of blood originating from the respiratory tract. The expectoration of blood from a source other than the respiratory tract is not defined as hemoptysis and would not be coded with ICD–10–CM diagnosis code R04.2 (Hemoptysis).

As stated in the proposed rule, ICD–10–CM diagnosis code R04. 2 (Hemoptysis) is currently assigned to MDC 04 (Diseases & Disorders of the Respiratory System), not MDC 05 (Diseases & Disorders of the Circulatory System). We proposed to add these procedures to MDC 04, to address the matter of these procedures producing assignment to MS–DRGs 981 through 983 when coded with this diagnosis.

We note that under this proposal ICD–10–PCS procedure codes 03LY0DZ, 03LY3DZ and 03LY4DZ will continue to also be assigned to several MS–DRGs in three other MDCs (including MDC 05 (Diseases & Disorders of the Circulatory System)) as discussed in the proposed rule. With the exception of the pre-

MDC, assignment to MDCs is driven by the principal diagnosis and not by the procedure. We also note that according to the ICD–10–CM Official Guidelines for Coding and Reporting, diagnoses described by codes from Chapter 18 (Symptoms, Signs and Abnormal Clinical and Laboratory Findings) of ICD–10–CM, such as R04.2, are acceptable for reporting when a related definitive diagnosis has not been established (confirmed) by the provider. If the expectoration of blood from the respiratory tract or another source is determined to be due another condition, that condition should be coded as principal diagnosis instead and assignment to a MDC will be driven by that principal diagnosis.

Our clinical advisors continue to believe that these procedures are also clearly related to ICD–10–CM diagnosis code R04.2 (Hemoptysis) assigned to MDC 04 and believe that it is appropriate to add these procedures to MDC 04. Therefore, after consideration of the public comments received, we are finalizing our proposal to add ICD–10–PCS procedure codes 03LY0DZ, 03LY3DZ and 03LY4DZ to MDC 04 in MS–DRGs 166, 167, and 168.

e. Acquired Coagulation Factor Deficiency With Percutaneous Artery Embolization

As discussed in the proposed rule, we received a request to reassign cases for acquired coagulation factor deficiency when reported with a procedure describing the complete occlusion of an artery with an intraluminal device from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) or 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System). The requestor asked that we reassign ICD–10–CM diagnosis code D68.4 (Acquired coagulation factor deficiency) from MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders) in MS–DRG 813 (Coagulation Disorders), to MDC 05. The requestor provided the following list of 59 ICD–10–PCS procedure codes describing the complete occlusion of an artery with an intraluminal device in its request for consideration to reassign the ICD–10–CM diagnosis code for acquired coagulation factor deficiency to MDC 05. The requester noted that the diagnosis of Hemorrhage, not elsewhere classified (ICD–10–CM diagnosis code R58) groups to MS–DRGs 252, 253 and 254 or 270, 271, and 272 in MDC 05 when reported with one of the 59 ICD–10–PCS procedure codes listed and requested that cases reporting a diagnosis describing acquired coagulation factor deficiency also group to those MS–DRGs when reported with one of the 59 ICD–10–PCS procedure codes listed.

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ICD-10-PCS Code	Code Description
02LQ3DZ	Occlusion right pulmonary artery with intraluminal device, percutaneous approach
02LR3DZ	Occlusion left pulmonary artery with intraluminal device, percutaneous approach
03L53DZ	Occlusion right axillary artery with intraluminal device, percutaneous approach
03L63DZ	Occlusion left axillary artery with intraluminal device, percutaneous approach
03L73DZ	Occlusion right brachial artery with intraluminal device, percutaneous approach
03L83DZ	Occlusion left brachial artery with intraluminal device, percutaneous approach
03L93DZ	Occlusion right ulnar artery with intraluminal device, percutaneous approach
03LB3DZ	Occlusion right radial artery with intraluminal device, percutaneous approach
03LC3DZ	Occlusion left radial artery with intraluminal device, percutaneous approach
03LD3DZ	Occlusion right hand artery with intraluminal device, percutaneous approach
03LF3DZ	Occlusion left hand artery with intraluminal device, percutaneous approach
03LY3DZ	Occlusion upper artery with intraluminal device, percutaneous approach
04LK3DZ	Occlusion right femoral artery with intraluminal device, percutaneous approach
04LL3DZ	Occlusion left femoral artery with intraluminal device, percutaneous approach
04LM3DZ	Occlusion right popliteal artery with intraluminal device, percutaneous approach
04LN3DZ	Occlusion left popliteal artery with intraluminal device, percutaneous approach
04LP3DZ	Occlusion right anterior tibial artery with intraluminal device, percutaneous approach
04LQ3DZ	Occlusion left anterior tibial artery with intraluminal device, percutaneous approach
04LR3DZ	Occlusion right posterior tibial artery with intraluminal device, percutaneous approach
04LS3DZ	Occlusion left posterior tibial artery with intraluminal device, percutaneous approach
04LT3DZ	Occlusion right peroneal artery with intraluminal device, percutaneous approach
04LU3DZ	Occlusion left peroneal artery with intraluminal device, percutaneous approach
04LV3DZ	Occlusion right foot artery with intraluminal device, percutaneous approach
04LW3DZ	Occlusion left foot artery with intraluminal device, percutaneous approach
03L03DZ	Occlusion right internal mammary artery with intraluminal device, percutaneous approach

ICD-10-PCS Code	Code Description
03L13DZ	Occlusion left internal mammary artery with intraluminal device, percutaneous approach
03L23DZ	Occlusion innominate artery with intraluminal device, percutaneous approach
03L33DZ	Occlusion right subclavian artery with intraluminal device, percutaneous approach
03L43DZ	Occlusion left subclavian artery with intraluminal device, percutaneous approach
03LG3DZ	Occlusion intracranial artery with intraluminal device, percutaneous approach
03LH3DZ	Occlusion right common carotid artery with intraluminal device, percutaneous approach
03LJ3DZ	Occlusion left common carotid artery with intraluminal device, percutaneous approach
03LK3DZ	Occlusion right internal carotid artery with intraluminal device, percutaneous approach
03LL3DZ	Occlusion left internal carotid artery with intraluminal device, percutaneous approach
03LM3DZ	Occlusion right external carotid artery with intraluminal device, percutaneous approach
03LN3DZ	Occlusion left external carotid artery with intraluminal device, percutaneous approach
03LP3DZ	Occlusion right vertebral artery with intraluminal device, percutaneous approach
03LQ3DZ	Occlusion left vertebral artery with intraluminal device, percutaneous approach
03LS3DZ	Occlusion right temporal artery with intraluminal device, percutaneous approach
03LT3DZ	Occlusion left temporal artery with intraluminal device, percutaneous approach
04L13DZ	Occlusion celiac artery with intraluminal device, percutaneous approach
04L23DZ	Occlusion gastric artery with intraluminal device, percutaneous approach
04L33DZ	Occlusion hepatic artery with intraluminal device, percutaneous approach
04L43DZ	Occlusion splenic artery with intraluminal device, percutaneous approach
04L53DZ	Occlusion superior mesenteric artery with intraluminal device, percutaneous approach
04L63DZ	Occlusion right colic artery with intraluminal device, percutaneous approach
04L73DZ	Occlusion left colic artery with intraluminal device, percutaneous approach
04L83DZ	Occlusion middle colic artery with intraluminal device, percutaneous approach
04L93DZ	Occlusion right renal artery with intraluminal device, percutaneous approach
04LA3DZ	Occlusion left renal artery with intraluminal device, percutaneous approach
04LB3DZ	Occlusion inferior mesenteric artery with intraluminal device, percutaneous approach
04LC3DZ	Occlusion right common iliac artery with intraluminal device, percutaneous approach
04LD3DZ	Occlusion left common iliac artery with intraluminal device, percutaneous approach
04LE3DZ	Occlusion right internal iliac artery with intraluminal device, percutaneous approach
04LF3DZ	Occlusion left internal iliac artery with intraluminal device, percutaneous approach

ICD-10-PCS Code	Code Description
04LH3DZ	Occlusion right external iliac artery with intraluminal device, percutaneous approach
04LJ3DZ	Occlusion left external iliac artery with intraluminal device, percutaneous approach
04LY3DZ	Occlusion lower artery with intraluminal device, percutaneous approach

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We stated our analysis of this grouping issue confirmed that, when diagnosis code D68.4 is reported as a principal diagnosis with one of the 59 ICD–10–PCS procedure codes provided by the requestor, these cases group to MS–DRGs 981, 982, and 983. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''. We examined the claims data to identify cases involving the 59 procedure codes in MDC 05 reported with a principal diagnosis of code D68.4 that are currently grouping to MS–DRGs 981, 982, and 983. Our analysis showed one case reported a principal diagnosis of D68.4 with a procedure code in MDC 05, with a length of stay of 2.0 days and costs of $21,890 in MS–DRG 981. We found zero cases in MS–DRGs 982 and 983 reporting a procedure code from MDC 05 and a principal diagnosis of code D68.4.

Overall, for MS–DRGs 981, 982 and 983, there was a total of one case reporting a principal diagnosis of acquired coagulation factor deficiency with any of the procedures from MDC 05 provided by the requestor, demonstrating that acquired coagulation factor deficiency is not typically corrected surgically by occlusion of an artery with an intraluminal device.

As discussed in the proposed rule, we also examined the data for cases in MS–DRG 813, and our findings are shown in this table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
813	All cases	16,680	4.7	$11,286
	Cases with principal diagnosis D68.4	142	6.4	$17,822

As shown in this table, there were a total of 16,680 cases in MS–DRG 813, with an average length of stay of 4.7 days and average costs of $11,286. In MS–DRG 813, we found 142 cases reporting a principal diagnosis of an acquired coagulation factor deficiency with an average length of stay of 6.41 days and average costs of $17,822. We note that the average costs for the subset of cases in MS–DRG 813 reporting a principal diagnosis of an acquired coagulation factor deficiency are higher than the average costs of all cases that currently group to MS–DRG 813.

We are clarifying in this final rule that cases reporting a principal diagnosis of acquired coagulation factor deficiency group to MS–DRGs 813, which is the medical MS–DRG that contains coagulation disorders, in the absence of a surgical procedure. We note that every diagnosis code is assigned to a medical MS–DRG to define the logic of the MS–DRG either as a principal or secondary diagnosis. As discussed in section II.E.12.a., certain procedure codes may affect the MS–DRG and result in a surgical MS–DRG assignment. Cases reporting a principal diagnosis of acquired coagulation factor deficiency group to MS–DRGs 799, 800 and 801 (Splenectomy with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 802, 803, and 804 (Other O.R. Procedures of the Blood and Blood Forming Organs with MCC, with CC, and without CC/MCC, respectively) in the presence of a surgical procedure such as the procedures listed by the requestor. We refer the reader to the ICD–10 MS–DRG Version 37 Definitions Manual for complete documentation of the logic for case assignment to surgical MS–DRGs 799, 800, 801, 802, 803, and 804 and to medical MS–DRG 813 (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*).

However, as stated in the proposed rule, our clinical advisors believe that diagnosis code D68.4 describes acquired bleeding disorders in which the affected person lacks the necessary coagulation factors for proper clot formation and wound healing, and therefore, is most clinically aligned with the diagnosis codes assigned to MDC 16 (where it is currently assigned). Our clinical advisors further note that a diagnosis of an acquired bleeding disorder is not comparable to conditions described by the ICD–10–CM code R58 (Hemorrhage, not elsewhere classified) as suggested by the requestor. Diagnoses described by codes from Chapter 18 (Symptoms, Signs and Abnormal Clinical and Laboratory Findings) of ICD–10–CM, such as R58, can be the result of a variety of underlying conditions, or describe conditions of an unexplained etiology. We stated that as an ill-defined condition, our clinical advisors do not believe it is appropriate to equate this diagnosis code with a bleeding disorder. Therefore, we did not propose to reassign ICD–10–CM diagnosis code D68.4 from MDC 16 to MDC 05.

Comments: Commenters agreed with CMS' proposal not to reassign ICD–10–CM diagnosis code D68.4 from MDC 16 to MDC 05. One commenter stated a diagnosis of an acquired bleeding disorder is not comparable to conditions described by the ICD–10–CM code R58, Hemorrhage, not elsewhere classified, and ICD–10–CM code D68.4 is most clinically aligned with the diagnosis codes in MDC 16.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to maintain the assignment of ICD–10–CM diagnosis code D68.4 in MDC 16.

f. Epistaxis with Percutaneous Artery Embolization

We received a request to consider adding cases for a hemorrhage of the nose when reported with a procedure describing percutaneous arterial embolization to MDC 03 (Disease and Disorders of the Ear, Nose, Mouth and Throat) in MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively). ICD–10–CM diagnosis code R04.0 (Epistaxis) is used to describe a hemorrhage of the nose or ''nosebleed'' and is currently assigned to MDC 03. ICD–10–PCS procedure codes describing percutaneous arterial embolization may be reported with procedure codes 03LM3DZ (Occlusion of right external carotid artery with intraluminal device, percutaneous approach), 03LN3DZ (Occlusion of left external carotid artery with intraluminal device, percutaneous approach), or 03LR3DZ (Occlusion of face artery with intraluminal device, percutaneous approach) and are currently assigned to several MS–DRGs in five MDCs as illustrated in the table.

MDC	MS-DRG	MS-DRG Description
01	020-022	Intracranial Vascular Procedures with PDX Hemorrhage
01	023-027	Craniotomy
05	270-272	Other Major Cardiovascular Procedures
11	673-675	Other Kidney and Urinary Tract Procedures
21	907-909	Other O.R. Procedures for Injuries
24	957-959	Other Procedures for Multiple Significant Trauma

According to the requestor, when diagnosis code R04.0 is reported as a principal diagnosis with any one of the procedure codes describing a percutaneous arterial embolization (03LM3DZ, 03LN3DZ, or 03LR3DZ), these cases are grouping to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

As stated in the proposed rule, our analysis of this grouping issue confirmed that, when epistaxis (ICD–10–CM diagnosis code R04.0) is reported as a principal diagnosis with ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ, these cases group to MS–DRGs 981, 982, and 983. The reason for this grouping is because whenever there is a surgical procedure reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.''

For our review of this grouping issue and the request to have cases reporting procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ added to MDC 03 in MS–DRGs 133 through 134, we first examined claims data from September 2019 update of the FY 2019 MedPAR file for cases reporting ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ with a principal diagnosis of R04.0 from MDC 03 that currently group to MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS code with PDX R04.0	Number of Cases	Average Length of Stay	Average Costs
981	03LM3DZ	19	7.32	$27,984
	03LN3DZ	28	9.36	$36,283
	03LR3DZ	3	4.67	$21,717
982	03LM3DZ	19	4.47	$24,195
	03LN3DZ	43	4.16	$18,698
	03LR3DZ	18	4.06	$17,665
983	03LM3DZ	9	3.44	$16,273
	03LN3DZ	6	1.50	$14,244
	03LR3DZ	1	3.00	$24,270

We then examined the claims data to identify the average length of stay and average costs for all cases in MS–DRGs 133 and 134. Our findings are shown in the table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
133	1,757	5.6	$15,337
134	849	2.5	$9,512

As shown in the table, for MS–DRG 133, there were a total of 1,757 cases with an average length of stay of 5.6 days and average costs of $15,337. For MS–DRG 134, there were a total of 849 cases with an average length of stay of 2.5 days and average costs of $9,512. Our clinical advisors believe that procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ are appropriate procedures to treat commonly occurring ear, nose, and throat bleeding diagnoses and expressed support for these procedure codes to group to MDC 03.

We noted that, as discussed in section II.D.4 of the preamble of the proposed rule and section II.E.4. of this final rule, we proposed to delete MS–DRGs 133 and 134 and create new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). Therefore, we proposed to add ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ to MDC 03 in new MS–DRGs 143, 144, and 145, if finalized. Under this proposal, cases reporting ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ with a principal diagnosis from MDC 03 would group to new MS–DRGs 143, 144, and 145.

The following table reflects our simulation for ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ in new MS–DRGs 143, 144, and 145.

MS-DRG	ICD-10-PCS code	Number of Cases	Average Length of Stay	Average Costs
143	All cases	709	8.06	$21,408
	03LM3DZ	31	10.60	$29,585
	03LN3DZ	37	8.70	$34,252
	03LR3DZ	10	6.40	$29,418
144	All cases	1,499	4.26	$12,931
	03LM3DZ	19	4.47	$24,195
	03LN3DZ	48	4.30	$18,719
	03LR3DZ	18	4.06	$17,665
145	All cases	1,004	2.42	$9,153
	03LM3DZ	10	3.7	$16,127
	03LN3DZ	7	1.4	$14,925
	03LR3DZ	1	3.00	$24,270

Comment: A commenter supported our proposal to add procedure codes describing a percutaneous arterial embolization to MDC 03. This commenter also stated CMS should expand ICD–10–PCS to include procedure codes describing the control of bleeding of the nasal passages performed using a percutaneous and percutaneous endoscopic approach so the resources involved in addressing acute or postprocedural bleeding in this manner can be assessed.

Response: We appreciate the commenter's support. As discussed in section II.E.16. of the preamble of this final rule, the ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. We encourage commenters to submit proposals for procedure coding changes via Email to: *ICDProcedureCodeRequest@cms.hhs.gov.*

Comment: Another commenter questioned CMS's proposal and stated these procedures should be classified to the circulatory MS–DRGs if the bleed is due to an artery or vessel and a procedure is performed on that artery/vessel.

Response: We appreciate the comment and concerns raised on our proposal.

As explained in the proposed rule, when conducting the review of procedures producing assignment to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, the objective is to identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls, or to move the principal diagnosis codes to the MDC in which the procedure falls.

As stated in the proposed rule, ICD–10–CM diagnosis code R04.0 (Epistaxis) is used to describe a hemorrhage of the nose or ''nosebleed'' and is currently assigned to MDC 03 (Diseases & Disorders of the Ear, Nose, Mouth & Throat), not MDC 05 (Diseases & Disorders of the Circulatory System). We proposed to add these procedures to MDC 03, to address the matter of these procedures producing assignment to MS–DRGs 981 through 983 when performed for a diagnosis of epistaxis.

We note that under this proposal ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ will continue to also be assigned to several MS–DRGs in five other MDCs (including MDC 05 (Diseases & Disorders of the Circulatory System)) as discussed in the proposed rule. With the exception of the pre-MDC, assignment to MDCs is driven by the principal diagnosis and not by the procedure. We also note that according

to the ICD–10–CM Official Guidelines for Coding and Reporting, diagnoses described by codes from Chapter 18 (Symptoms, Signs and Abnormal Clinical and Laboratory Findings) of ICD–10–CM, such as R04.0, are acceptable for reporting when a related definitive diagnosis has not been established (confirmed) by the provider. If the nasal bleeding is determined to be due another condition, that condition should be coded as principal diagnosis instead and assignment to a MDC will be driven by that principal diagnosis. Our clinical advisors continue to believe that these procedures are also clearly related to the principal diagnoses ICD–10–CM diagnosis code R04.0 (Epistaxis), assigned to MDC 03 and believe that it is appropriate to add these procedures to MDC 03.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ to MDC 03 in new MS–DRGs 143, 144, and 145. We refer the reader to section II.E.4. of this final rule for the comments regarding our proposal to create new MS–DRGs 143, 144, and 145, as well as our finalization of that proposal.

g. Revision or Removal of Synthetic Substitute in Peritoneal Cavity

As discussed in the proposed rule, during our review of the cases that group to MS–DRGs 981 through 983, we noted that when several ICD–10–PCS procedure codes describing revision or removal of synthetic substitute in the peritoneal cavity are reported in conjunction with ICD–10–CM diagnosis codes in MDC 01 (Diseases and Disorders of the Nervous System), such as complications of intracranial shunts, the cases group to MS–DRGs 981 through 983. ICD–10–PCS procedure codes 0WWG0JZ (Revision of synthetic substitute in peritoneal cavity, open approach), 0WWG4JZ (Revision of synthetic substitute in peritoneal cavity, percutaneous endoscopic approach), and 0WPG0JZ (Removal of synthetic substitute from peritoneal cavity, open approach) are currently assigned to MDC 06 (Diseases and Disorders of the Digestive System) in MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

As stated in the proposed rule, we examined cases that reported a principal diagnosis in MDC 01 and procedure code 0WWG0JZ, 0WWG4JZ, or 0WPG0JZ that currently group to MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Revision or Removal of Synthetic Substitute in Peritoneal Cavity with a Principal Diagnosis in MDC 01

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981	77	8.1	$24,463
982	170	4.1	$14,162
983	37	3.6	$11,543

Within MDC 01, our clinical advisors believe that these procedures, which describe revision or removal of synthetic substitute in peritoneal cavity, are most clinically similar to those in MS–DRGs 031, 032, and 033 (Ventricular Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). We therefore examined the data for all cases in MS–DRGS 031, 032, and 033.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
031	844	10.4	$30,275
032	1,898	4.3	$16,257
033	2,604	2.2	$12,601

The average costs for the subset of cases in MS–DRGs 981, 982, and 983 that report procedures describing revision or removal of synthetic substitute in the peritoneal cavity with a principal diagnosis from MDC 01 are lower than the average costs of cases in MS–DRGs 031, 032, and 033 as a whole, and the average length of stay for this subset of cases is also lower in two of the MS–DRGs and higher in one. Our clinical advisors believe the procedure codes describing revision or removal of synthetic substitute in the peritoneal cavity are clearly related to the principal diagnosis codes describing complications of intracranial shunts and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs (031, 032, and 033) as the principal diagnoses describing complications of intracranial shunts. We proposed to add ICD–10–PCS procedure codes 0WWG0JZ, 0WWG4JZ, and 0WPG0JZ to MDC 01 (Diseases and Disorders of the Nervous System) in MS–DRGs 031, 032, and 033.

Comments: Commenters supported our proposal to add ICD–10–PCS procedure codes 0WWG0JZ, 0WWG4JZ, and 0WPG0JZ to MDC 01 (Diseases and Disorders of the Nervous System) in MS–DRGs 031, 032, and 033. One commenter stated that ICD–10–PCS procedure codes describing revision or removal of synthetic substitute in the peritoneal cavity are related to the principal diagnosis codes describing complications of intracranial shunts, and so it is appropriate for the procedures to group to the same MS–

DRGs as the principal diagnoses describing complications of intracranial shunts. Another commenter noted that another indication for shunt revision is most commonly complications of ventriculoperitoneal shunts, and ICD–10–CM diagnosis codes describing complication of the ventriculoperitoneal shunts are assigned to MDC 01.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add ICD–10–PCS procedure codes 0WWG0JZ, 0WWG4JZ, and 0WPG0JZ to MDC 01 (Diseases and Disorders of the Nervous System) in MS–DRGs 031, 032, and 033.

h. Revision of Totally Implantable Vascular Access Devices

As discussed in the proposed rule, during our review of the cases currently grouping to MS–DRGs 981 through 983, we noted that when procedure codes describing Totally Implantable Vascular Access Devices (TIVADs) are reported with ICD–10–CM diagnosis codes assigned to MDC 04 (Diseases and Disorders of the Respiratory System), MDC 06 (Diseases and Disorders of the Digestive System), MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas), MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), MDC 13 (Diseases and Disorders of the Female Reproductive System), or MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders), the cases group to MS–DRGs 981 through 983.

TIVADs are port catheter devices inserted for chemotherapy treatment. The nine ICD–10–PCS procedure codes describing TIVADs are listed in this table.

ICD-10-PCS Code	Description
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach
0JH80WZ	Insertion of totally implantable vascular access device into abdomen subcutaneous tissue and fascia, open approach
0JHD0WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach
0JHF0WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach
0JHG0WZ	Insertion of totally implantable vascular access device into right lower arm subcutaneous tissue and fascia, open approach
0JHH0WZ	Insertion of totally implantable vascular access device into left lower arm subcutaneous tissue and fascia, open approach
0JHL0WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach
0JHM0WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach
0JHP0WZ	Insertion of totally implantable vascular access device into left lower leg subcutaneous tissue and fascia, open approach

We examined claims data to identify the average length of stay and average costs for cases in MS–DRGs 981 through 983 reporting ICD–10–PCS procedure codes describing TIVADs in conjunction with a principal diagnosis from MDCs 04, 06, 07, 08, 13, or 16. Our findings are shown in the following table.

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Insertion of Totally Implantable Vascular Access Devices				
MDC	**MS-DRG**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
04	981	427	10.3	$22,526
	982	244	6.5	$13,661
	983	11	3.4	$8,761
06	981	259	10.3	$24,003
	982	281	6.9	$13,712
	983	15	3.1	$9,688
07	981	172	10.3	$22,176
	982	113	6.3	$13,227
	983	2	3.5	$7,471
08	981	32	12.2	$24,424
	982	38	7.8	$16,531
	983	2	7.5	$16,693
13	981	38	11.3	$22,095
	982	43	7.5	$14,858
	983	0	-	$ -
16	981	30	10.1	$23,765
	982	64	6.4	$16,726
	983	15	5.2	$26,932

We stated our clinical advisors believe that cases reporting TIVADs with a principal diagnosis in MDCs 04, 06, 07, 08, 13, or 16 would most suitably group to the MS–DRGs describing ''Other'' procedures for each of these MDCs. These TIVAD procedures cannot be assigned to the specific surgical MS–DRGs within these MDCs since they are not performed on the particular anatomical areas described by each of the specific surgical MS–DRGs. For example, in MDC 04, TIVADs could not be assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) because they are not major chest procedures.

We therefore examined the claims data for each of these MS–DRGs. Our findings are shown in the following table.

MDC	MS-DRG	MS-DRG Description	Number of Cases	Average Length of Stay	Average Costs
04	166	Other Respiratory System O.R. Procedures with MCC, with CC, without CC/MCC respectively	11,380	10.3	$26,702
	167		6,575	4.9	$13,556
	168		2,189	2.6	$10,149
06	356	Other Digestive System O.R. Procedures with MCC, with CC, without CC/MCC respectively	7,525	10.4	$30,071
	357		5,759	5.8	$16,452
	358		1,191	3.4	$10,031
07	423	Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, without CC/MCC respectively	825	12.2	$29,944
	424		362	6.8	$16,588
	425		59	3.5	$11,158
08	515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, without CC/MCC respectively	4,655	8.2	$22,176
	516		13,308	4.6	$14,225
	517		11,992	2.6	$10,318
13	749	Other Female Reproductive System O.R. Procedures with CC/MCC, without CC/MCC respectively	695	8	$21,582
	750		99	2.9	$10,907
16	802	Other O.R. Procedures of the Blood and Blood Forming Organs with MCC, with CC, without CC/MCC respectively	849	10.1	$25,238
	803		894	5.2	$13,689
	804		414	2.5	$9,503

In the proposed rule, we noted that while the average costs and length of stay are similar in some cases and in some cases vary between the subset of cases currently grouping to MS–DRGs 981 through 983 and the cases currently grouping to the MS–DRGs describing ''Other'' procedures as set forth in the table, our clinical advisors noted that TIVADs are frequently inserted in order to administer chemotherapy for a variety of malignancies. MDCs 04, 06, 07, 08, 13, or 16 each contain ICD–10–CM diagnosis codes that describe a variety of malignancies. Therefore, our clinical advisors believe that the TIVAD procedures are clearly related to the principal diagnoses within MDCs 04, 06, 07, 08, 13, and 16. For the reasons previously indicated, our clinical advisors believe that cases reporting TIVADs with a principal diagnosis in MDCs 04, 06, 07, 08, 13, or 16 would mostly suitably group to the MS–DRGs describing ''Other'' procedures for each of these MDCs.

Therefore, we proposed to add the nine ICD–10–PCS procedure codes describing TIVADs as set forth in the table to the MS–DRGs describing ''Other'' procedures within each of MDCs 04, 06, 07, 08, 13, and 16, specifically: MDC 04 in MS–DRGs 166, 167, and 168, MDC 06 in MS–DRGs 356, 357, and 358, MDC 07 in MS–DRGs 423, 424, and 425, MDC 08 in MS–DRGs 515, 516, and 517, MDC 13 in MS–DRGs 749 and 750, and MDC 16 in MS–DRGs 802, 803, and 804. Under this proposal, cases reporting a principal diagnosis in MDCs 04, 06, 07, 08, 13, or 16 with a TIVAD procedure would group to the respective MS–DRGs within the MDC.

Comments: Commenters supported the addition of ICD–10–PCS procedure codes describing insertion of totally implantable vascular access devices to the MS–DRGs describing ''Other'' procedures within MDCs 04, 06, 07, 08, 13, and 16.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add the nine ICD–10–PCS procedure codes describing TIVADs as set forth in the table to the MS–DRGs describing ''Other'' procedures within each of MDCs 04, 06, 07, 08, 13, and 16, specifically: MDC 04 in MS–DRGs 166, 167, and 168, MDC 06 in MS–DRGs 356, 357, and 358, MDC 07 in MS–DRGs 423, 424, and 425, MDC 08 in MS–DRGs 515, 516, and 517, MDC 13 in MS–DRGs 749 and 750, and MDC 16 in MS–DRGs 802, 803, and 804.

i. Multiple Trauma With Internal Fixation of Joints

As discussed in the proposed rule, for FY 2020, we received a request to reassign cases involving diagnoses that identify multiple significant trauma combined with internal fixation of joint procedures from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma). The requestor provided an example of several ICD–10–CM diagnosis codes that together described multiple significant trauma in conjunction with ICD–10–PCS procedure codes beginning with the prefix ''0RH'' and ''0SH'' that describe internal fixation of upper and lower joints. The requestor provided several suggestions to address this reassignment, including: Adding all ICD–10–PCS procedure codes from MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) with the exception of codes that group to MS–DRG 956 (Limb Reattachment, Hip and Femur Procedures for Multiple Significant

Trauma) to MS DRGs 957, 958, and 959; adding codes with the prefix ''0RH'' and ''0SH'' to MDC 24; and adding ICD–10–PCS procedure codes from all MDCs except those that currently group to MS–DRG 955 (Craniotomy for Multiple Significant Trauma) or MS–DRG 956 (Limb Reattachment, Hip and Femur Procedures for Multiple Significant Trauma) to MS–DRGs 957, 958, and 959 in MDC 24. In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that we believe any potential reassignment of these cases requires significant analysis. We therefore did not propose any changes to the cases identified by the requestor.

For FY 2021, as the first step of the comprehensive analysis needed to assess the reassignment of cases involving diagnoses that identify multiple significant trauma combined with internal fixation of joint procedures, we stated in the proposed rule, our clinical advisors reviewed the list of procedure codes in the ''0RH'' and ''0SH'' code ranges, as suggested by the requestor. Our clinical advisors identified 161 ICD–10–PCS codes, which are listed in table 6P.1f., that they believe are clinically related to diagnoses assigned to MDC 24. We examined the claims data for cases that would be assigned to MDC 24 based on their diagnoses, but currently group to MS–DRGs 981 through 983 based on the presence of procedure codes in the ''0RH'' and ''0SH'' code ranges. Our findings are shown in this table.

ICD-10-PCS Code	Code Description	Number of Cases	Length of Stay	Cost
0SHB04Z	Insertion of internal fixation device into left hip joint, open approach	1	4	$54,446
0SH834Z	Insertion of internal fixation device into left sacroiliac joint, percutaneous approach	1	14	$30,992
0SH334Z	Insertion of internal fixation device into lumbosacral joint, percutaneous approach	1	6	$22,118
0RH634Z	Insertion of internal fixation device into thoracic vertebral joint, percutaneous approach	1	11	$56,631
0RH634Z	Insertion of internal fixation device into thoracic vertebral joint, percutaneous approach	1	10	$72,331
0RH604Z	Insertion of internal fixation device into thoracic vertebral joint, open approach	1	8	$15,857
0SH834Z	Insertion of internal fixation device into left sacroiliac joint, percutaneous approach	1	12	$32,489
0SHB04Z	Insertion of internal fixation device into left hip joint, open approach	1	3	$7,015

In the proposed rule, we noted that we found only 8 claims, with varying lengths of stay and average costs. We also examined the claims data for all cases in MS–DRGs 957, 958, and 959. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
957	1,966	13.2	$54,771
958	1,605	8.2	$30,701
959	114	5	$20,563

The very small number of claims we identified for cases that would be assigned to MDC 24 based on their diagnoses, but grouped to MS–DRGs 981 through 983 based on the presence of procedure codes in the ''0RH'' and ''0SH'' code ranges, have varying resource use relative to MS–DRGs 957, 958, and 959 as a whole. The average costs of the cases found in MS–DRGs 981–983 range from $7,015 to $72,331 with average lengths of stay ranging from 3 days to 14 days. The average costs of the cases found in MS–DRGs 957–959 range from $20,563 to $54,771 with average lengths of stay ranging from 5 days to 13.2 days. We stated given the nature of trauma cases, the resource use would be expected to vary based on the nature of the patient's injuries. In addition, as noted, our clinical advisors believe that these procedure codes are clinically related to the diagnoses in MDC 24. Therefore, we proposed to add the 161 ICD–10–PCS codes shown in Table 6P.1f associated with the proposed rule to MDC 24 in MS–DRGs 957, 958, and 959. Under this proposal, cases that would be assigned to MDC 24 based on their diagnoses, that also report one of the 161 ICD–10–PCS codes included in table 6P.1f, will group to MDC 24 in MS–DRGs 957, 958, and 959, rather than to MS–DRGs 981 through 983.

In the proposed rule, we noted that while we made this proposal to address the grouping issue for internal fixation of upper and lower joint procedures identified by the requestor, our clinical advisors believe that a more comprehensive analysis is required within MDC 24 to address the differences in severity level of diagnoses as well as the assignment of procedure codes to the MS–DRGs within MDC 24. We plan to continue this comprehensive analysis in future rulemaking.

Comment: Commenters supported our proposal to add the 161 ICD–10–PCS codes shown in Table 6P.1f to MDC 24 in MS–DRGs 957, 958, and 959. A commenter specifically stated they endorse the proposal as a means of more accurately representing the costs associated with the care and treatment of multi trauma patients. Commenters also stated they agreed that a more comprehensive analysis of the diagnoses and procedures assigned to MDC 24 should be undertaken.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add the 161 ICD–10–PCS codes shown in Table 6P.1f associated with this final rule to MDC 24 in MS–DRGs 957, 958, and 959. Accordingly, cases that would be assigned to MDC 24 based on their diagnoses, that also report one of the 161 ICD–10–PCS codes included in table 6P.1f, will group to MDC 24 in MS–DRGs 957, 958, and 959 under the ICD–10 MS–DRGs Version 38, effective October 1, 2020. As noted in the proposed rule, we plan to continue this comprehensive analysis in future rulemaking.

j. Reassignment of Procedures Among MS–DRGs 981 Through 983 and 987 Through 989

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

Based on the results of our review of claims data in the September 2019 update of the FY 2019 MedPAR file, we proposed to reassign three procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). We also proposed to reassign three procedure codes from MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively).

In conducting our review of the request to designate ICD–10–PCS procedure code 0W3G0ZZ (Control bleeding in peritoneal cavity, open approach) as an O.R. procedure (as described in section II.E.11.c.5. of this final rule), our clinical advisors noted that ICD–10–PCS codes 0W3G3ZZ (Control bleeding in peritoneal cavity, percutaneous approach) and 0W3G4ZZ (Control bleeding in peritoneal cavity, percutaneous endoscopic approach) are currently assigned to MS–DRGs 981 through 983 when reported with a principal diagnosis that is not assigned to one of the MDCs to which these procedure codes are assigned. We stated that our clinical advisors believe that these procedures would be more appropriately assigned to MS–DRGs 987 through 989 because they are on average less complex and difficult than the same procedure performed by an open approach, and therefore should be assigned to the ''less extensive'' DRG. Therefore, we proposed to reassign ICD–10–PCS codes 0W3G3ZZ and 0W3G4ZZ from MS–DRGs 981 through 983 to 987 through 989.

Comment: A commenter supported our proposal.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–PCS codes 0W3G3ZZ and 0W3G4ZZ from MS–DRGs 981 through 983 to 987 through 989, effective October 1, 2020.

In conducting our review of the request to designate ICD–10–PCS procedure codes 0WBC4ZX (Excision of mediastinum, percutaneous endoscopic approach, diagnostic) and 0WBC3ZX (Excision of mediastinum, percutaneous approach, diagnostic) as O.R. procedures (as described in section II.E.11.c.1. of this final rule), our clinical advisors noted that ICD–10–PCS code 0WBC0ZX (Excision of mediastinum, open approach, diagnostic) is currently assigned to MS–DRGs 981 through 983 when reported with a principal diagnosis that is not assigned to one of the MDCs to which the procedure code is assigned. We stated that our clinical advisors believe that this procedure would be more appropriately assigned to MS–DRGs 987 through 989 because this assignment is consistent with the assignment of other procedures that describe excision of the mediastinum performed by an open, percutaneous, or percutaneous endoscopic approach, and is consistent with the proposal for procedure codes 0WBC4ZX and 0WBC3ZX (with diagnostic qualifier) as discussed in section II.E.11.c.1. of this final rule. Therefore, we proposed to reassign ICD–10–PCS code 0WBC0ZX from MS–DRGs 981 through 983 to 987 through 989.

Comment: A commenter supported our proposal.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–PCS code 0WBC0ZX from MS–DRGs

981 through 983 to 987 through 989, effective October 1, 2020.

As discussed in the proposed rule, we received a request to examine cases reporting a procedure describing the open excision of gastrointestinal body parts in the gastrointestinal body system. The requester stated that when procedures describing the open excision of a specific gastrointestinal body part in the gastrointestinal body system are reported with a principal diagnosis such as C49.A3 (Gastrointestinal stromal tumor of small intestine (GIST)), the cases are assigned to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). However, when procedures describing the excision of a general gastrointestinal body part in the gastrointestinal body system are reported with the same principal diagnosis of GIST, the cases are assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). The requestor stated that procedures describing a specific body part value should be assigned to the same MS–DRG as procedures describing a general body part value.

The requestor provided four ICD–10–PCS procedure codes in its request. These four ICD–10–PCS procedure codes, as well as their MDC assignments, are listed in the table:

ICD-10-PCS Code	Code Description	MDC
0DB90ZZ	Excision of duodenum, open approach	06,07,17
0DBA0ZZ	Excision of jejunum, open approach	06
0DBB0ZZ	Excision of ileum, open approach	06
0DB80ZZ	Excision of small intestine, open approach	05,06,10,17,21,24

In the proposed rule, we noted that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42120 through 42122), we finalized our proposal to move seven ICD–10–CM diagnosis codes describing gastrointestinal stromal tumors (GIST), including C49.A3, from MDC 08 to MDC 06, under the ICD–10 MS–DRGs Version 37, effective October 1, 2019. As a result, cases reporting a principal diagnosis of GIST and a procedure code that is assigned to MDC 06 (such as ICD–10–PCS codes 0DBA0ZZ, 0DBB0ZZ, 0DB80ZZ, and 0DB90ZZ) group to MS–DRGs in MDC 06.

We stated in the proposed rule that our analysis of this grouping issue found that these four ICD–10–PCS codes describing related procedures have dissimilar designations that determine whether and in what way the presence of the procedure impacts the MS–DRG assignment. We noted ICD–10–PCS code 0DB80ZZ is classified as an extensive O.R. procedure and ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ are classified as non-extensive O.R. procedures. As a result, whenever ICD–10–PCS code 0DB80ZZ is reported with a principal diagnosis that is assigned to a different MDC than the procedure code, the case would be assigned to MS–DRGs 981 through 983. When ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ, or 0DBB0ZZ are reported with a principal diagnosis that is assigned to a different MDC than the procedure code, the case would be assigned to MS–DRGs 987 through 989.

We examined the claims data to identify cases reporting procedure code 0DB80ZZ that are currently grouping to MS–DRGs 981, 982 and 983. Our findings are shown in this table:

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Excision of Small Intestine, Open Approach				
MS-DRG	ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
981	All cases	25,914	11.4	$31,281
	0DB80ZZ	66	15.8	$42,198
982	All cases	13,990	6.2	$17,714
	0DB80ZZ	21	8.9	$16,995
983	All cases	2,572	3	$12,194
	0DB80ZZ	4	3	$10,619

We also examined the claims data to identify cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ that are currently grouping to MS–DRGs 987, 988 and 989. Our findings are shown in this table:

MS-DRGs 987 – 989: Cases Reporting Procedures Describing Excision of Duodenum, Jejunum, or Ileum, Open Approach				
MS-DRG	ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
987	All cases	8,266	10.3	$23,442
	0DB90ZZ	2	25	$78,148
	0DBA0ZZ	5	8.2	$39,885
	0DBB0ZZ	30	17.5	$36,683
988	All cases	7,566	5.7	$12,426
	0DB90ZZ	1	6	$5,438
	0DBA0ZZ	3	7.7	$14,713
	0DBB0ZZ	41	10.9	$22,876
989	All cases	1,140	3	$8,095
	0DB90ZZ	0	0	$0
	0DBA0ZZ	2	2	$5,087
	0DBB0ZZ	27	6.8	$10,775

We stated the results of our data analysis indicated that cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ describing the open excision of a specific gastrointestinal body part in MS–DRGs 987, 988, and 989 generally have a longer length of stay and higher average costs when compared to all the cases in their assigned MS–DRG. The subset of cases reporting 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ and the subset of cases in MS–DRGs 981, 982 and 983 reporting 0DB80ZZ are more closely aligned in terms of the lengths of stay and average costs. Further we stated, our clinical advisors believed that, given the similarity in resource use required for procedures describing an open excision of a gastrointestinal body part in terms of the use of an operating room, anesthesia and skills required, for clinical coherence and consistency in assignment with ICD–10–PCS code 0DB80ZZ, it would be appropriate to also designate ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ as extensive O.R. procedures.

Therefore, we proposed to change the designation of ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ from non-extensive O.R. procedures to extensive O.R. procedures for FY 2021. Under this proposal, cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ, which are unrelated to the MDC to which the case would otherwise be assigned based on the principal diagnosis, will group to MS–DRGs 981, 982 and 983.

Comment: A commenter supported our proposal to change the designation of the three procedure codes so that when cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ, which are unrelated to the MDC to which the case would otherwise be assigned based on the principal diagnosis, will group to MS–DRGs 981, 982 and 983 instead of MS–DRGs 987, 988, and 989.

Response: We appreciate the commenter's support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ from non-extensive O.R. procedures to extensive O.R. procedures, effective October 1, 2020.

11. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non-O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R.

procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures to be newly designated as O.R. procedures. As discussed in section II.E.13. of the preamble of this final rule, we are making Table 6B.—New Procedure Codes—FY 2021 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We also refer readers to the ICD–10 MS–DRG Version 37 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index. In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multi-year project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS–DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

We will provide more detail on this analysis and the methodology for conducting this review in future rulemaking. As we noted in the FY 2020 IPPS/LTCH PPS rulemaking, as we continue to develop our process and methodology, as previously noted, we are soliciting recommendations on other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs. Therefore, in the FY 2021 proposed rule, we again solicited feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. We stated commenters should submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by October 20, 2020.

In this FY 2021 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to this discussion in the proposed rule.

Comment: Several commenters supported CMS' plan to continue to conduct the comprehensive, systematic review of the ICD–10–PCS codes that includes a process for determining when a procedure is designated as O.R. or Non-O.R. and acknowledged the magnitude of the potential impact to significantly restructure MS–DRGs.

Response: We thank the commenters for their support and appreciate their acknowledgement of the magnitude of this effort.

Comment: Two commenters stated that the public feedback they submitted by November 1, 2019 in response to CMS' request for feedback in the FY 2020 IPPS/LTCH PPS proposed rule was not stated in the FY 2021 IPPS/LTCH proposed rule.

Response: CMS appreciates the comments submitted in response to our request for feedback in both the FY 2020 IPPS/LTCH PPS proposed rule and in the FY 2021 IPPS/LTCH PPS proposed rule. While the comments submitted by the November 1, 2019 deadline were not specifically addressed in the FY 2021 IPPS/LTCH PPS proposed rule, feedback on what factors and/or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system will be included when we provide more detail on this analysis and the methodology for conducting this comprehensive review in future rulemaking.

Comment: Several commenters requested that CMS consider the drivers of complexity and resource consumption surrounding the entire procedure and not only O.R. charges. The commenters stated that while large hospitals may have hybrid operating rooms or specialized procedure rooms (for example, interventional radiology suites), many smaller community hospitals may have multi-purpose O.R.s where the same room may be used for invasive general surgeries as well as procedures that may be performed in specialized procedure rooms in large hospitals. One of these commenters provided an example of the complexity and resource consumption of a procedure performed in a catheterization lab and stated that O.R verses Non O.R. may not be the most critical differentiator of resource consumption. Another commenter urged CMS to consider the definition of a ''significant procedure'' as defined in the Uniform Hospital Discharge Data Set (UHDDS) which states, ''A significant procedure is one that is: Surgical in nature; carries a procedural risk; carries an aesthetic risk; or requires specialized training.'' This commenter stated that this definition does not include whether an ''O.R.'' is required, but in many cases, the procedure itself determines if it is ''surgical in nature'' and other procedures that do not require an

''O.R.'' do require specialized training or carry risk.

Response: CMS appreciates the commenters' feedback and recommendations as to factors to consider in evaluating O.R. designations. As stated previously, we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room. We agree with commenters and believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. As discussed in the proposed rule, we are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We continue to develop our process and methodology, and will provide more detail in future rulemaking.

Comment: Several commenters suggested that CMS assemble an advisory panel comprised of clinical, coding and financial stakeholders, physician specialty societies and experts to review methodologies for O.R. determination and that CMS should address procedures performed in all settings as there may be variations based on geographical differences, hospital size, resources and physician specialty availability. Two commenters suggested that CMS allow sufficient time for provider review and stated that thorough data analysis with provider input is critical to allow for appropriate insight in provider comments. These commenters stated that outside of the CMS noted intentions for consideration, additional data for each ICD–10–PCS procedure code should be provided so that a more thorough analysis can be completed. One of these commenters further suggested revising the October 20 deadline for submission of public comments if CMS could not provide the additional data timely.

Response: CMS appreciates this feedback. While CMS has already convened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts, we look forward to further collaboration with the industry. As discussed in section II.D.1.b. of the preamble of the proposed rule, given the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and in order to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. Therefore, changing the deadline to October 20th of each year would allow CMS the additional time for the review and consideration of any proposed updates. However, as stated in section II.E.1.b. of this final rule, we are maintaining the deadline of November 1, 2020 for the submission of such requests for FY 2022. Recognizing sufficient time is needed to provide feedback on what factors or criteria to consider in determining whether a procedure should be designated as an O.R. procedure in the ICD–10–PCS classification system, we have provided opportunity for the public to provide feedback beginning with the FY 2018 final rule and we continue to solicit input. We encourage the public to submit comments on other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs timely for consideration. Once we are in a position to provide more detail on this analysis and the methodology for conducting this comprehensive review in future rulemaking, the public will again have the opportunity to provide feedback.

In the FY 2021 IPPS/LTCH PPS proposed rule and this final rule, we are addressing requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or changing the designation from O.R. procedure to non-O.R. procedure. In this section of the rule we discuss the process that was utilized for evaluating the requests that were received for FY 2021 consideration. For each procedure, our clinical advisors considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a nonextensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of this rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In cases where we proposed to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also proposed one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, if requestors included some or all of MS–DRGs 981 through 989 in their request or included MS–DRGs that require the presence of any O.R. procedure, we did not specifically address that aspect in summarizing their request or our response to the request in this section of this rule.

For procedures that would not typically require the resources of an operating room, our clinical advisors determined if the procedure should affect the MS–DRG assignment.

As indicated in the proposed rule, we received several requests to change the designation of specific ICD–10–PCS procedure codes from non-O.R. procedures to O.R. procedures, or to change the designation from O.R. procedures to non-O.R. procedures. In this section of this rule, as we did in the proposed rule, we detail and respond to some of those requests and, further, summarize and respond to the public comments we received in response to our proposals, if applicable. With regard to the remaining requests, as stated in the proposed rule, our clinical advisors believe it is appropriate to consider these requests as part of our comprehensive review of the procedure codes as previously discussed.

b. O.R. Procedures to Non-O.R. Procedures

(1) Endoscopic Revision of Feeding Devices

One requestor identified three ICD–10–PCS procedure codes that describe endoscopic revision of feeding devices, shown in the following table.

ICD-10-PCS Code	Code Description
0DW08UZ	Revision of feeding device in upper intestinal tract, via natural or artificial opening endoscopic
0DW68UZ	Revision of feeding device in stomach, via natural or artificial opening endoscopic
0DWD8UZ	Revision of feeding device in lower intestinal tract, via natural or artificial opening endoscopic

In the ICD–10 MS–DRG Version 37 Definitions Manual, these three ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor noted that these procedures would not require the resources of an operating room and that they consume resources comparable to related ICD–10–PCS procedure codes describing the endoscopic insertion of feeding tubes that currently are designated as Non-O.R. procedures.

In the proposed rule, we stated that we agreed with the requestors that these procedures do not typically require the resources of an operating room, and are not surgical in nature. Therefore, we proposed to remove 0DW08UZ, 0DW68UZ, and 0DWD8UZ from the FY 2021 ICD–10 MS–DRGs Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. We stated in the proposed rule that, under this proposal, these procedures would no longer impact MS–DRG assignment.

Comments: Commenters supported our proposal to designate ICD–10–PCS procedure codes 0DW08UZ, 0DW68UZ, 0DWD8UZ as non-O.R. procedures. One commenter specifically stated they believed that the endoscopic revision of feeding devices does not typically require the resources of an O.R. and can be safely performed in non-O.R. settings such as interventional radiology or endoscopy suites.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0DW08UZ, 0DW68UZ, and 0DWD8UZ from O.R. procedures to non-O.R. procedures, effective October 1, 2020.

c. Non-O.R. Procedures to O.R. Procedures

(1) Percutaneous/Endoscopic Biopsy of Mediastinum

One requestor identified ICD–10–PCS procedure code 0WBC4ZX (Excision of mediastinum, percutaneous endoscopic approach, diagnostic) that describes a percutaneous endoscopic biopsy of the mediastinum that the requestor stated is performed in the operating room under general anesthesia, requires an incision through the chest wall, insertion of a mediastinoscope in the space between the lungs and involves removal of a tissue sample. The requestor recommended that all procedures performed within the mediastinum by an open or percutaneous endoscopic approach, regardless of whether it is a diagnostic or therapeutic procedure, should be designated as O.R. procedures because the procedures require great skill and pose risks to patients due to the structures contained within the mediastinum. The requestor noted that the mediastinum contains loose connective tissue, the heart and great vessels, esophagus, trachea, nerves, and lymph nodes. The requestor further noted that redesignating these procedures from non-O.R. to O.R. would provide compensation for operating room resources and general anesthesia.

We note that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description. In response to the requestor's suggestion that all procedures performed within the mediastinum by an open or percutaneous endoscopic approach, regardless of whether it is a diagnostic or therapeutic procedure should be designated as an O.R. procedure, we examined the following procedure codes:

ICD-10-PCS Code	Description
0WBC0ZX	Excision of mediastinum, open approach, diagnostic
0WBC0ZZ	Excision of mediastinum, open approach
0WBC3ZX	Excision of mediastinum, percutaneous approach, diagnostic
0WBC3ZZ	Excision of mediastinum, percutaneous approach
0WBC4ZX	Excision of mediastinum, percutaneous endoscopic approach, diagnostic
0WBC4ZZ	Excision of mediastinum, percutaneous endoscopic approach

In the ICD–10 MS–DRGs Definitions Manual Version 37, procedure codes 0WBC0ZX, 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ are currently designated as O.R. procedures, however, procedure codes 0WBC3ZX and 0WBC4ZX are not recognized as O.R. procedures for purposes of MS–DRG assignment. We stated in the proposed rule that we agree with the requestor that procedure code 0WBC4ZX would typically require the resources of an operating room. We further stated that our clinical advisors also agree that procedure code 0WBC3ZX would typically require the resources of an operating room. Therefore, we proposed to add these 2 procedure codes to the FY 2021 ICD–10 MS–DRGs Version 38 Definitions Manual in Appendix E- Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory

System); MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

As previously noted, procedure codes 0WBC0ZX, 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ are currently designated as O.R. procedures. As displayed in the FY 2020 ICD–10 MS–DRGs Version 37 Definitions Manual in Appendix E-Operating Room Procedures and Procedure Code/MS–DRG Index, these procedure codes are assigned to several MS–DRGs across many MDCs. During our process of reviewing potential MDC and MS–DRG assignments for procedure codes 0WBC3ZX and 0WBC4ZX, our clinical advisors recommended that we reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from their current MS–DRG assignments in MDC 04 (Diseases and Disorders of the Respiratory System). Procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ are currently assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) and procedure code 0WBC0ZX is assigned to MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We stated in the proposed rule that according to our clinical advisors, procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ would be more appropriately and clinically aligned with the same MS–DRG assignment as procedure code 0WBC0ZX, which is also consistent with the assignment for other procedures performed on the mediastinum. Therefore, we proposed to reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ to MS–DRGs 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

Comment: Commenters supported the proposal to reclassify ICD–10–PCS procedure codes 0WBC4ZX (Excision of mediastinum, percutaneous endoscopic approach, diagnostic) and 0WBC3ZX (Excision of mediastinum, percutaneous approach, diagnostic) as O.R. procedures for the purposes of MS–DRG assignment for FY 2021. A commenter stated their belief that surgeries performed within the mediastinum by an open or percutaneous endoscopic approach, regardless of whether it is a diagnostic or therapeutic procedure, typically require the resources of the O.R. to control for possible damage to the structures contained within the mediastinum, including loose connective tissue, the heart and great vessels, esophagus, trachea, nerves, and lymph nodes. The commenter noted that the invasive nature of these procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection.

Commenters also supported the proposal to reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from MS–DRGs 163, 164, and 165 to MS–DRGs 166, 167, and 168. However, a couple commenters did not agree with the proposal and stated that the open, percutaneous, and endoscopic therapeutic mediastinal excisions should remain distinct from the diagnostic mediastinal procedures. The commenters noted that while the approaches of the procedures are the same, the time, risk and resource utilization is different for the therapeutic and diagnostic procedures. The commenters stated that diagnostic procedures require only a small mediastinal resection, more specifically an incisional biopsy, for diagnostic purposes while the therapeutic mediastinal resection involves the complete resection of large tumors, cysts or masses that may be malignant or benign juxtaposed to critical mediastinal structures. In addition, the commenters reported that therapeutic mediastinal resections will often require more time in the O.R., slightly longer lengths of stay, and more post-operative care due to the invasive nature of the procedures.

Response: We appreciate the commenters' feedback on the proposal to reclassify ICD–10–PCS procedure codes 0WBC4ZX and 0WBC3ZX as O.R. procedures for the purposes of MS–DRG assignment and on the proposal to reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from MS–DRGs 163, 164, and 165 to MS–DRGs 166, 167, and 168. In response to the commenters who did not agree with the proposal to reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from MS–DRGs 163, 164, and 165 to MS–DRGs 166, 167, and 168, as noted by the commenters, the approaches of the therapeutic and diagnostic procedures are the same, however our clinical advisors did not agree that the time, risk and resource utilization are necessarily different for the therapeutic and diagnostic procedures.

While the commenters' asserted that therapeutic mediastinal procedures will often require more time in the O.R., slightly longer lengths of stay, and more post-operative care due to the invasive nature of the procedures, our analysis of claims data found that the average length of stay and the average costs for the diagnostic procedures were greater than those of the therapeutic procedures. We examined data from the September 2019 update of the FY 2019 MedPAR data for both diagnostic and therapeutic mediastinal excision procedures across all MS–DRGs. Our findings are shown in the table below.

ICD-10-PCS Code	Description	Number of Cases	Average Length of Stay	Average Costs
0WBC0ZX	Excision of mediastinum, open approach, diagnostic	1,141	8.2	$21,279
0WBC3ZX	Excision of mediastinum, percutaneous approach, diagnostic			
0WBC4ZX	Excision of mediastinum, percutaneous endoscopic approach, diagnostic			
0WBC0ZZ	Excision of mediastinum, open approach	291	4.3	$17,267
0WBC3ZZ	Excision of mediastinum, percutaneous approach			
0WBC4ZZ	Excision of mediastinum, percutaneous endoscopic approach			

As shown in the table, there were a total of 1,141 cases reporting a diagnostic excision of mediastinum procedure with an average length of stay of 8.2 days and average costs of $21,279 and a total of 291 cases reporting a therapeutic excision of mediastinum procedure with an average length of stay of 4.3 days and average costs of $17,267. Our clinical advisors maintain that therapeutic and diagnostic procedures involving excision of the mediastinum are clinically aligned and should be grouped together. However, as noted in prior rule making (84 FR 42148), our clinical advisors recognize that MS–DRGs 163, 164, 165, 166, 167, and 168 may warrant further review and therefore, we plan to begin this more detailed review beginning with our FY 2022 MS–DRG classification analysis of claims data and determine what modifications may need to be considered for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to add procedure codes 0WBC4ZX and 0WBC3ZX as O.R. procedures to the FY 2021 ICD–10 MS–DRGs Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System); MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively). We are also finalizing our proposal to reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from MS–DRGs 163, 164, and 165 to MS–DRGs 166, 167, and 168, effective FY 2021.

One requestor identified ICD–10–PCS procedure code 3E0L4GC (Introduction of other therapeutic substance into pleural cavity, percutaneous endoscopic approach) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that talc pleurodesis via video-assisted thoracoscopic surgery (VATS), involves placing a thoracoscope through the chest wall for visualization, then placing a port and injecting talc, doxycycline, or other chemical into the pleural cavity under general anesthesia and should therefore be recognized as an O.R. procedure for purposes of MS–DRG assignment.

We stated in the proposed rule that we agreed with the requestor that ICD–10–PCS procedure code 3E0L4GC typically requires the resources of an operating room. We also note that the AHA published Coding Clinic advice in 2015 that instructed to code both ICD–10–PCS procedure codes 0BJQ4ZZ (Inspection of pleura, percutaneous endoscopic approach) and 3E0L3GC (Introduction of other therapeutic substance into pleural cavity, percutaneous approach) for thoracoscopic chemical pleurodesis. In the publication, code 0BJQ4ZZ, recognized as an O.R. procedure for purposes of MS–DRG assignment, was instructed to be reported for the video-assisted thoracoscopic portion of the procedure since the endoscopic component of the procedure could not be captured by the approach values available at the time. In FY 2018, the approach value ''4'' Percutaneous Endoscopic was added to the root operation Introduction table 3E0, to capture percutaneous endoscopic administration of a therapeutic substance, meaning that code 0BJQ4ZZ was no longer needed along with code 3E0L3GC to report thoracoscopic chemical pleurodesis. Only code 3E0L4GC is needed to report all components of the procedure. Designating code 3E0L4GC as an O.R. procedure for purposes of MS–DRG assignment classifies the procedure as intended when two codes were needed to fully code the procedure. Therefore, we proposed to add procedure code 3E0L4GC to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. procedures with MCC, CC, without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System); and MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System).

Comments: Commenters supported our proposal to designate ICD–10–PCS procedure code 3E0L4GC as an O.R. procedure. A commenter noted that

since code 0BJQ4ZZ, Inspection of pleura, percutaneous endoscopic approach, is no longer necessary as an additional code to capture the endoscopic component of the procedure it makes sense for code 3E0L4GC to be designated as an O.R. procedure.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure code 3E0L4GC from non-O.R. procedure to O.R. procedure, effective October 1, 2020.

(3) Percutaneous Endoscopic Excision of Stomach

One requestor identified ICD–10–PCS procedure code 0DB64ZZ (Excision of stomach, percutaneous endoscopic approach) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that percutaneous endoscopic excisions of gastric lesions and percutaneous endoscopic partial gastrectomies are performed in the operating room under general anesthesia, use comparable resources, and are designated as O.R. procedures. Therefore, the requestor stated that this procedure should also be recognized as O.R. procedure for purposes of MS–DRG assignment.

We stated in the proposed rule that we agreed with the requestor that ICD–10–PCS procedure code 0DB64ZZ typically requires the resources of an operating room. During our review, we also noted that ICD–10–PCS code 0DB64ZX (Excision of stomach, percutaneous endoscopic approach, diagnostic) was not currently recognized as an O.R. procedure. We proposed to add these codes to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 619, 620, and 621 (Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); and MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major Procedure with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with CC/MCC and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms).

Comments: Many commenters supported our proposal. One commenter specifically stated they concurred with the requestor's statement that similar procedures such as percutaneous endoscopic excisions of gastric lesions and percutaneous endoscopic partial gastrectomies are currently classified as O.R. procedures, and that the two listed stomach excision codes should be designated as O.R. procedures due to comparable costs and resource use. This commenter also stated they believed that the invasive nature of such procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0DB64ZZ and 0DB64ZX from non-O.R. procedures to O.R. procedures, effective October 1, 2020.

As discussed in the proposed rule, during our review, we also noted that ICD–10–PCS procedure code 0DB64Z3 (Excision of stomach, percutaneous endoscopic approach, vertical (sleeve)), which is clinically similar to ICD–10–PCS codes 0DB64ZZ and 0DB64ZX, is designated as an O.R. procedure assigned to the same MS–DRGs as we proposed for ICD–10–PCS codes 0DB64ZZ and 0DB64ZX, as well as to MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries, with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. procedures for multiple significant trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma). We stated our clinical advisors believe that principal diagnoses in MDCs 05 and 21 are typically not indications for procedures describing percutaneous endoscopic excision of stomach and that ICD–10–PCS procedure code 0DB64Z3 should be assigned to the same MS–DRGs as ICD–10–PCS codes 0DB64ZZ and 0DB64ZX.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file to determine if there were any cases that reported 0DB64Z3 and were assigned to MDC 05, MDC 21, or MDC 24. The following table shows our findings:

MDC 05 and MDC 21: Cases Reporting Procedures Describing Percutaneous Endoscopic Excision of Stomach, Vertical (Sleeve)

MDC	MS-DRG		Number of Cases	Average Length of Stay	Average Costs
05	264	All Cases	9,666	9.1	$22,637
		0DB64Z3	6	9.5	$32,579
21	907	All Cases	9,622	9.6	$28,026
		0DB64Z3	2	3.0	$14,281
	908	All Cases	8,498	5.2	$14,647
		0DB64Z3	5	1.2	$11,788
	909	All Cases	2,797	3	$10,073
		0DB64Z3	1	2.0	$6,887

We found zero cases in MS–DRGs 957, 958, and 959 reporting 0DB64Z3 and a principal diagnosis in MDC 24 (Multiple Significant Trauma). We stated our analysis demonstrated that diagnoses assigned to MDC 05, MDC 21, and MDC 24 are not typically corrected surgically by percutaneous endoscopic vertical (sleeve) gastrectomy given the small number of cases reporting this procedure in these MDCs. We also stated our clinical advisors believe procedure codes describing the percutaneous endoscopic excision of stomach should have the same MDC assignments in the ICD–10 MS–DRGs Version 38 for coherence. Therefore, we proposed to remove the assignments of code 0DB64Z3 from MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries, with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. procedures for multiple significant trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

Comments: Commenters supported our proposal and stated they agreed that diagnoses assigned to MDC 05 (Diseases and Disorders of the Circulatory System), MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs), and MDC 24 (Multiple Significant Trauma) are not typically corrected surgically by percutaneous endoscopic vertical (sleeve) gastrectomy, and that procedure codes describing the percutaneous endoscopic excision of stomach should all be assigned to the same MDCs.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the assignments of code 0DB64Z3 from MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries, with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. procedures for multiple significant trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma), effective October 1, 2020.

Lastly, we stated while we were reviewing this request, we noted inconsistencies in how procedures involving the excision of stomach are designated. Excision of stomach codes differ by approach and qualifier. ICD–10–PCS procedure codes describing excision of stomach with similar approaches have been assigned different attributes in terms of designation as an O.R. or Non-O.R. procedure. We identified the following five related codes:

ICD-10-PCS Code	Code Description
0DB63Z3	Excision of stomach, percutaneous approach, vertical
0DB63ZZ	Excision of stomach, percutaneous approach
0DB67Z3	Excision of stomach, via natural or artificial opening, vertical
0DB67ZZ	Excision of stomach, via natural or artificial opening
0DB68Z3	Excision of stomach, via natural or artificial opening endoscopic, vertical

As discussed in the proposed rule, in the ICD–10 MS–DRGs Version 37, these ICD–10–PCS codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment, while similar excision of stomach procedure codes with the same approach but different qualifiers are recognized as Non-O.R. procedures. We stated our clinical advisors indicated that these procedures are not surgical in nature and do not require an incision. Therefore, we proposed to remove ICD–10–PCS procedure codes 0DB63Z3, 0DB63ZZ, 0DB67Z3, 0DB67ZZ, and 0DB68Z3 from the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

Comments: Commenters opposed our proposal. A few commenters noted that the five procedure codes describing excision of stomach listed are similar in nature to procedure codes 0DB64ZZ and 0DB64ZX that describe percutaneous endoscopic excisions of the stomach, which CMS proposed to change from non-O.R. procedures to O.R. procedures. One commenter also stated that procedure codes describing excision of stomach via percutaneous approach or excision of stomach via percutaneous endoscopic approach should have the same O.R. procedure designation.

Response: We appreciate the comments and concerns raised on our proposal.

Our clinical advisors continue to indicate that these procedures are not surgical in nature and do not require an incision however, after acknowledging the concerns raised by commenters, believe it would be appropriate to take additional time to review the inconsistencies in how procedures involving the excision of stomach are designated. Therefore, after consideration of public comments, we are not finalizing our proposal to remove ICD–10–PCS procedure codes 0DB63Z3, 0DB63ZZ, 0DB67Z3, 0DB67ZZ, and 0DB68Z3 from the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Accordingly, these procedures will continue to impact MS–DRG assignment under the ICD–10 MS–DRGs Version 38, effective October 1, 2020.

(4) Percutaneous Endoscopic Drainage

One requestor identified six ICD–10–PCS procedure codes that describe procedures involving laparoscopic drainage of peritoneum, peritoneal cavity, and gallbladder that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table:

ICD-10-PCS Code	Code Description
0D9W4ZZ	Drainage of peritoneum, percutaneous endoscopic approach
0D9W40Z	Drainage of peritoneum with drainage device, percutaneous endoscopic approach
0W9G4ZZ	Drainage of peritoneal cavity, percutaneous endoscopic approach
0W9G40Z	Drainage of peritoneal cavity with drainage device, percutaneous endoscopic approach
0F944ZZ	Drainage of gallbladder, percutaneous endoscopic approach
0F9440Z	Drainage of gallbladder with drainage device, percutaneous endoscopic approach

The requestor stated these procedures would commonly be performed under general anesthesia and require the resources of an operating room. The requestor also noted that similar procedures such as percutaneous endoscopic inspection of gallbladder, percutaneous endoscopic excision of peritoneum and percutaneous endoscopic extirpation of matter from peritoneal cavity are currently classified as O.R. procedures in Version 37 of the ICD–10 MS–DRGs and that the six listed procedure codes should be designated as O.R. procedures due to comparable costs and resource use.

We stated in the proposed rule that we agreed with the requestor that the six ICD–10–PCS procedure codes listed in the table typically require the resources of an operating room. Therefore, to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we proposed to add codes 0D9W4ZZ and 0D9W40Z as O.R. procedures assigned to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); and MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs). We also proposed to add codes 0W9G4ZZ and 0W9G40Z as O.R. procedures assigned to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 420, 421, and 422 (Hepatobiliary Diagnostic Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas); MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract); MS–DRGs 749 and 750 (Other Female Reproductive System Procedures with and without CC/MCC, respectively) in MDC 13 (Diseases and Disorders of the Female Reproductive System); MS–DRGs 802, 803, and 804 (Other O.R. Procedures of the Blood and Blood Forming Organs, with MCC, with CC, and without CC/MCC, respectively) in MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major Procedure with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs). Lastly, we proposed to add codes 0F944ZZ and 0F9440Z as O.R. procedures assigned to MS–DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E., with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas).

Comments: Commenters supported our proposal. One commenter stated they concurred with the requestor's statement that similar procedures such as percutaneous endoscopic inspection of gallbladder, percutaneous endoscopic excision of peritoneum and percutaneous endoscopic extirpation of matter from peritoneal cavity are currently classified as O.R. procedures, and that the six listed procedure codes should be designated as O.R. procedures due to comparable costs and resource use. The commenter also stated they believed that the invasive nature of such procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection. Other commenters stated they agreed all ICD–10–PCS procedure codes describing procedures involving laparoscopic drainage of peritoneum, peritoneal cavity, or gallbladder should be designated as O.R. procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of ICD–10–PCS procedure codes 0D9W4ZZ, 0D9W40Z, 0W9G4ZZ 0W9G40Z, 0F944ZZ and 0F9440Z from non-O.R. procedures to O.R. procedures, effective October 1, 2020.

As discussed in the proposed rule, during our review of this request, we identified related ICD–10–PCS procedure code 0F944ZX (Drainage of gallbladder, percutaneous endoscopic approach, diagnostic) that is also currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. We stated that our clinical advisors believe that similar to the six procedure codes submitted by the requester, this procedure typically requires the resources of an operating room and should have the same attributes in Version 38 for coherence. Therefore, we proposed to add code 0F944ZX as an O.R. procedure assigned to MS–DRGs 420, 421 and 422 (Hepatobiliary Diagnostic Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas) to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

Comments: Commenters supported our proposal and as previously mentioned stated they agreed all ICD–10–PCS procedure codes describing procedures involving laparoscopic drainage of the peritoneum, peritoneal cavity, or gallbladder should be designated as O.R. procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of 0F944ZX from non-O.R. procedure to O.R. procedure, effective October 1, 2020.

In the proposed rule, we stated during our review, we also identified the related ICD–10–PCS procedure codes 0F940ZZ (Drainage of gallbladder, open approach), 0F940ZX (Drainage of gallbladder, open approach, diagnostic) and 0F9400Z (Drainage of gallbladder with drainage device, open approach). Our analysis found that the ICD–10–PCS codes describing drainage of gallbladder have dissimilar MDC assignments. Procedure codes 0F940ZZ and 0F940ZX are currently assigned to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System) and MS–DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E, with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas). However, ICD–10–PCS procedure code 0F9400Z is currently assigned to MS–DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E, with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas) alone. We stated our clinical advisors believe that principal diagnoses in MDC 06 are typically not indications for procedures describing the drainage of gallbladder. We examined claims data from the September 2019 update of the FY 2019 MedPAR file to determine if there were any cases that reported procedure codes 0F940ZZ or 0F940ZX and were assigned to MDC 06. We found zero cases in MS–DRGs 356, 357, and 358 reporting code 0F944ZZ or 0F940ZX and a principal diagnosis in MDC 06 (Diseases and Disorders of the Digestive System), demonstrating that diagnoses in MDC 06 are not typically corrected surgically by drainage of the gallbladder. Our clinical advisors believe procedure codes describing the drainage of gallbladder should have the same MDC assignments in Version 38 for coherence. Therefore, we proposed to remove procedure codes 0F940ZZ and 0F940ZX from MS–DRGs 356, 357, and 358 in MDC 06 (Diseases and Disorders of the Digestive System).

Comments: Commenters supported our proposal and stated they agreed that procedure codes describing the drainage of the gallbladder should be assigned to the same MDC.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove procedure codes 0F940ZZ and 0F940ZX from MS–DRGs 356, 357, and 358 in MDC 06 (Diseases and Disorders of the Digestive System), effective October 1, 2020.

As stated in the proposed rule, our further analysis of this request identified the nine ICD–10–PCS codes in the following table describing drainage of the peritoneum, peritoneal cavity, or gallbladder:

ICD-10-PCS Code	Code Description
0D9W00Z	Drainage of peritoneum with drainage device, open approach
0D9W0ZX	Drainage of peritoneum, open approach, diagnostic
0D9W0ZZ	Drainage of peritoneum, open approach
0D9W4ZX	Drainage of peritoneum, percutaneous endoscopic approach, diagnostic
0W9G00Z	Drainage of peritoneal cavity with drainage device, open approach
0W9G0ZZ	Drainage of peritoneal cavity, open approach
0F9400Z	Drainage of gallbladder with drainage device, open approach
0F940ZZ	Drainage of gallbladder, open approach
0F940ZX	Drainage of gallbladder, open approach, diagnostic

We noted that these procedures are currently classified as extensive O.R. procedures. Our clinical advisors have noted that treatment practices have shifted since the initial O.R. procedure designations. We stated our clinical advisors believe that, given the similarity in factors such as complexity, resource utilization, and requirement for anesthesia administration between procedures describing the drainage of the peritoneum, peritoneal cavity, and gallbladder, it would be more appropriate to designate these nine ICD–10–PCS codes as non-extensive O.R. procedures. Therefore, we also proposed to change the designation of ICD–10–PCS codes 0D9W00Z, 0D9W0ZX, 0D9W0ZZ, 0D9W4ZX, 0W9G00Z, 0W9G0ZZ, 0F9400Z, 0F940ZZ and 0F940ZX from extensive O.R. procedures to non-extensive O.R. procedures for FY 2021.

Comment: A commenter supported our proposal to designate the nine ICD–10–PCS codes describing drainage of the peritoneum, peritoneal cavity, or gallbladder that are currently classified as extensive O.R. procedures as non-extensive O.R. procedures.

Response: We appreciate the commenter's support.

Comment: One commenter opposed CMS' proposal and stated location should be factored in. The commenter stated the designation of these procedures should differ depending if the procedure was performed in an operating room versus a radiology suite versus a procedure room. The commenter also stated procedures performed via an open approach should be designated as extensive O.R. procedures and procedures performed via a percutaneous endoscopic approach should be designated as non-extensive O.R. procedures. This same commenter specifically opposed changing the designation of procedure codes that describe the open drainage of the peritoneal cavity from extensive O.R. to non-extensive O.R. procedure and believed the designation should depend on how deep the open drainage incision site is.

Response: We do not agree that unilaterally all open procedures should be designated as extensive O.R. procedures and procedures performed laparoscopically should be designated

as non-extensive O.R. procedures. While the site in which the procedure is performed and the procedural approach are important considerations in the designation of a procedure, there are other clinical factors such as procedure complexity, resource utilization, and need for anesthesia administration that should also be considered. In this regard, our clinical advisors believe the nine ICD–10–PCS codes that describe the drainage of the peritoneum, peritoneal cavity, and gallbladder, regardless of approach, are generally less complex than other procedures designated as extensive O.R. procedures.

Also, we are not clear what the commenter means when they state that ''the designation of procedure codes describing the open drainage of the peritoneum should depend on how deep the open drainage incision site is''. The peritoneum is defined as the smooth transparent serous membrane that lines the cavity of the abdomen. Procedure codes for the open drainage of the peritoneum are used to describe any procedure where the skin or mucous membrane and any other body layers necessary to expose the peritoneum are cut through to take or let out fluid and/or gases. Any anatomical differences from patient to patient that might factor into the technical complexity of the procedure, such as habitus, would be captured in the ICD–10–CM diagnosis coding.

In the absence of a compelling clinical rationale for maintaining the designation of these procedures as extensive O.R. procedures, our clinical advisors continue to believe that, given the similarity in factors such as complexity, resource utilization, and requirement for anesthesia administration between procedures describing the drainage of the peritoneum, peritoneal cavity, and gallbladder, it would be more appropriate to designate these nine ICD–10–PCS codes as non-extensive O.R. procedures. Therefore, after consideration of the public comments we received, we are finalizing our proposal to change the designation of ICD–10–PCS codes 0D9W00Z, 0D9W0ZX, 0D9W0ZZ, 0D9W4ZX, 0W9G00Z, 0W9G0ZZ, 0F9400Z, 0F940ZZ and 0F940ZX from extensive O.R. procedures to non-extensive O.R. procedures, effective October 1, 2020.

(5) Control of Bleeding

One requestor identified ICD–10–PCS procedure code 0W3G0ZZ (Control bleeding in peritoneal cavity, open approach) that describes a procedure in which the bleeding source within the peritoneal cavity is controlled by cautery, clips, and/or suture through an open abdominal incision with direct visualization of the surgical site, that the requestor stated requires the resources of an operating room and general anesthesia but is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor also noted that ICD–10–PCS procedure codes 0W3F0ZZ (Control bleeding in abdominal wall, open approach), 0W3H0ZZ (Control bleeding in retroperitoneum, open approach), and 0W3J0ZZ (Control bleeding in pelvic cavity, open approach) describe procedures to control bleeding in various anatomic sites and are currently classified as O.R. procedures.

We stated in the proposed rule that we agree with the requestor that it would be clinically appropriate to redesignate procedure code 0W3G0ZZ as an O.R. procedure consistent with procedure codes 0W3F0ZZ, 0W3H0ZZ and 0W3J0ZZ, that also describe procedures performed to control bleeding and are designated as O.R. procedures. Therefore, we proposed to add procedure code 0W3G0ZZ to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRG 264 (Other Circulatory O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 423, 424, and 425 (Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas); MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with and without CC/MCC, respectively) in MDC 21 ((Injuries, Poisonings and Toxic Effects of Drugs); MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma) and to MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

Comment: Commenters agreed with the proposed redesignation of ICD–10–PCS procedure code 0W3G0ZZ as an O.R. procedure, and stated this would be consistent with similar procedure codes describing control of bleeding in other anatomic sites.

Response: We thank the commenters for their support.

After consideration of the public comments received, we are finalizing our proposal to add ICD–10–PCS procedure code 0W3G0ZZ to the ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to the MDCs and MS–DRGs noted earlier in this section, effective October 1, 2020.

(6) Inspection of Penis

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32549), one requestor stated that ICD–10–PCS procedure code 0VJS0ZZ (Inspection of penis, open approach) is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that there are circumstances that warrant inpatient admission for open exploration of the penis, such as to rule out penile fracture and extravasation due to trauma. The requestor stated their belief that because this procedure involves an open incision for exploration of penile structures and utilizes general anesthesia in the operating room, it would be appropriately classified as an O.R. procedure. In the proposed rule, we stated that we agreed with the requestor that ICD–10–PCS procedure code 0VJS0ZZ typically requires the resources of an operating room. Therefore, we proposed to add ICD–10–PCS procedure code 0VJS0ZZ to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E-Operating Room procedures and procedure code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 709 (Penis Procedures with CC/MCC) and 710 (Penis Procedures without CC/

MCC) in MDC 12 (Diseases and Disorders of the Male Reproductive System).

Comments: Several commenters supported CMS' proposal to reclassify ICD–10–PCS procedure code 0VJS0ZZ from a non-O.R. procedure to an O.R procedure for purposes of MS–DRG assignment for MS–DRGs 709 and 710.

Response: We appreciate the commenters' support.

After consideration of the public comments received, we are finalizing our proposal to add ICD–10–PCS procedure code 0VJS0ZZ (Inspection of penis, open approach) to the FY2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure to MS–DRGs 709 (Penis Procedures with CC/MCC) and 710 (Penis Procedures without CC/MCC) in MDC 12 (Diseases and Disorders of the Male Reproductive System) for FY2021 effective October 1, 2020.

12. Changes to the MS–DRG Diagnosis Codes for FY 2021

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a non-CC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16- (Resistance to antimicrobial drugs) from a non-CC to a CC. We stated that postponing adoption of the comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the severity level designation changes for FY 2020.

c. Guiding Principles for Making Changes to Severity Levels

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of the methodology to measure the impact on resource use. It also provided an opportunity for CMS to receive public input on this analysis and to address any questions in order to assist the public in formulating written comments on the current severity level designations for consideration in the FY 2021 rulemaking. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the data describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

Following the listening session, we further considered the public comments received and reconvened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts to identify guiding principles to apply in evaluating whether changes to the severity level designations of diagnoses are needed and to ensure the severity designations appropriately reflect resource use based on review of the claims data, as well as consideration of relevant clinical factors (for example, the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses) and improve the overall accuracy of the IPPS payments. In the proposed rule, we stated our goal was to develop a set of guiding principles that, when applied, could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances. The workgroup identified the following nine guiding principles as meaningful indicators of expected resource use by a secondary diagnosis.

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.

- Reflects systemic impact.
- Post-operative condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We stated in the FY 2021 IPPS/LTCH PPS proposed rule that we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of these guiding principles, and present the findings and proposals in future rulemaking. We invited public comments regarding these guiding principles, as well as other possible ways we could incorporate meaningful indicators of clinical severity. When providing additional feedback or comments, we encouraged the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

Comment: Many commenters supported the guiding principles. Commenters stated the application of the nine guiding principles, as laid out in the proposed rule, rather than solely relying on a mathematical analysis of claims data is a reasoned approach in addressing the concerns raised last year. A commenter specifically stated they acknowledge and appreciate CMS' recognition that the transition to ICD–10–CM, and the significant changes that have occurred to diagnosis codes since the FY 2008 review, warrants a comprehensive CC/MCC analysis.

Response: We thank the commenters for their support.

Comment: Some commenters noted general concerns with the guiding principles. Commenters stated that the nine guiding principles appeared to be open to interpretation or differences in clinical opinion and do not provide clear logic for decision-making. Other commenters stated that it was not clear how CMS will apply these guiding principles in conjunction with the mathematical analyses of claims data to make decisions about severity levels. These commenters stated that more information is needed to better understand CMS's process for decision making on the designation of diagnosis severity levels.

Response: We thank the commenters for sharing their concerns.

The nine guiding principles are not criteria, intended to turn the analysis into a quantitative exercise, but instead to provide a framework for assessing relevant clinical factors. As patients present with a variety of diagnoses, in examining the secondary diagnoses, we would consider what additional resources are required, above and beyond those that are already being utilized to address the principal diagnosis and/or other secondary diagnoses that might also be present on the claim. The goal of our comprehensive analysis is to create stratification for reimbursing inpatient hospitalization in the fewest amount of categories with the most explanatory power in a clinically cohesive way.

Our intended approach is first, CMS will use these guiding principles in making an initial clinical assessment of the appropriate severity level designation for each ICD–10–CM code as a secondary diagnosis. CMS will then use a mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule to determine if the presence of the ICD–10–CM code as a secondary diagnosis appears to, or does not appear to, increase hospital resource consumption. There may be instances in which we would decide that the clinical analysis weighs in favor of proposing to maintain or proposing to change the severity designation of an ICD–10–CM code after application of the nine guiding principles.

Comment: Some commenters stated that the guiding principles appeared to be more applicable to MCC conditions, were too strict and could potentially eliminate CC conditions. A commenter stated that the application of the guiding principles would represent a substantial revision to the definition of a CC, noting MS–DRG Definition Manual Version 37.1 provides the following definition: ''A substantial complication or comorbidity was defined as a condition that because of its presence with a specific principal diagnosis would cause an increase in length of stay by at least one day in at least 75 percent of the patients.'' A few commenters highlighted individual ICD–10–CM diagnoses and stated these conditions warrant assignment into CC or MCC MS–DRGs based on certain clinical criteria.

Response: We appreciate the commenters' feedback.

We do not believe the nine guiding principles would be mostly applicable, or only applicable, to MCC conditions. In applying the nine guiding principles in our review of the appropriate severity level designation, the intention is not to require that a diagnosis code satisfy each principle, or a specific number of principles in assessing whether to designate a secondary diagnosis code as a non-CC versus a CC versus a MCC. Rather, the severity level determinations would be based on the consideration of the clinical factors captured by these principles as well as the empirical analysis of the additional resources associated with the secondary diagnosis.

We wish to clarify that the definition of a ''substantial complication or comorbidity'' from the MS–DRG Definition Manual that the commenter referenced, is the definition of a CC that was used in Version 8 of the DRGs. In FY 2008, for Version 25 of the MS–DRGs, the diagnoses comprising the CC list were completely redefined and instead each CC was categorized as a major CC or a CC (that is, non-major CC) based on relative resource use. As stated previously, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. We also wish to clarify that there is a difference between the non-CC, CC, or MCC designation of an individual diagnosis code and the requirements for GROUPER assignment into a severity split MS–DRG. MS–DRG assignment is a different issue and is based on GROUPER logic and the other codes reported on a claim.

Comment: A commenter encouraged the use of the APR–DRG GROUPER to analyze severity levels for individual diagnoses and in conjunction with certain principal diagnoses to reinforce change decisions or identify conflicts requiring re-evaluation. Some commenters questioned how conditions such as obstetrical diagnoses or congenital conditions would, or would not, be considered in the application of the guiding principles.

Response: We thank the commenters for sharing their input and suggestions.

The Medicare GROUPER is for the Medicare population and is not designed to account for all populations like the APR–DRG GROUPER, so we generally do not believe it would be appropriate to use the APR–DRG GROUPER severity of illness and risk of mortality scores to analyze severity levels as they relate to Medicare inpatient prospective payment. In regards to obstetric conditions, given the limited number of cases reporting ICD–10–CM obstetrical codes in the Medicare claims data, we are considering use of datasets other than MedPAR cost data, as we indicated in the FY 2020 IPPS/LTCH PPS final rule

(84 FR 42152), to be used in addition to the application of these guiding principles for future evaluation of severity level designation for the ICD–10–CM diagnosis codes from the Obstetrics chapter of the ICD–10–CM classification. In contrast, the diagnosis codes from the Congenital Malformations, Deformities and Chromosomal Abnormalities Chapter of the ICD–10–CM classification may be used throughout the life of the patient. Our internal workgroup believe the nine guiding principles are applicable to these conditions and these codes lend themselves to review using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of these guiding principles.

In this FY 2021 IPPS/LTCH PPS final rule, we present a summation of the comments we received for each of the nine guiding principles and our responses to those comments. We thank commenters for sharing their views and their willingness to support CMS in our efforts to continue a comprehensive CC/MCC analysis.

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.

Comment: A commenter opposed this principle and stated that decisions in these patients are complex, especially when being guided by family members as part of 'person and community engagement' which hospitals are scored on under the Value Based Purchasing program. This commenter expressed concern that a family may insist on continued use of resources that CMS then determines it will not pay for, placing the financial burden onto the hospital.

Response: We note the target of our analysis is on individual ICD–10–CM codes, as secondary diagnosis codes, as they relate to inpatient prospective payment. While we appreciate the commenters' concern, we note that in certain instances, conditions that denote end of life or near death may conversely also decrease resource use as the decision to withdraw care is made. We also note that the impact of the secondary diagnosis is dependent on the principal diagnosis reported, with which it is associated. If the secondary diagnosis is reported with a principal diagnosis that reflects serious illness with treatment complexity, then the marginal contribution of the secondary diagnosis to the overall resource use may actually be relatively small. In applying these principles as part of the clinical analysis of the appropriate severity level designation for each ICD–10–CM code as a secondary diagnosis, CMS will take this into consideration.

- Denotes organ system instability or failure.

Comments: Commenters supported this guiding principle.

Response: We appreciate the commenters' support.

- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.

Comments: Some commenters opposed this principle and stated this principle may not be able to be applied across the board as many ICD–10–CM diagnosis codes do not distinguish exacerbation. The commenters stated there are conditions that have separate acute and chronic diagnosis codes, combined acute/chronic concepts into single diagnosis codes, and some conditions for which the diagnosis code does not indicate the specificity of acute or chronic.

Response: All ICD–10–CM diagnosis codes, including codes that do not explicitly describe acute exacerbations, would be reviewed using this guiding principle to assess the degree to which the individual ICD–10–CM diagnosis code as a secondary diagnosis affects hospital resource consumption, to determine if the severity designation is more appropriately non-CC, CC, or MCC. The intention is again, not to require that every diagnosis code satisfy each principle, but instead to identify relevant clinical factors to help denote if, and to what degree, additional resources are required above and beyond those that are already being utilized to address the principal diagnosis and/or other secondary diagnoses that might also be present on the claim.

- Serves as a marker for advanced disease states across multiple different comorbid conditions.

Comment: A few commenters noted that this guiding principle is open to interpretation.

Response: A marker is a clinical measurement that is associated with or believed to be related pathophysiologically to a clinical outcome and can serve as an indicator for health or disease. While we appreciate that assessing relevant clinical factors will depend on the particular diagnosis codes at issue, our clinical advisors believe this principle, along with the other 8 principles, would provide appropriate parameters for our clinical review.

- Reflects systemic impact.

Comment: A commenter noted that many current CC or MCC diagnoses are limited to a single body system and therefore, stated it is unclear what the guideline means by ''systemic impact.''

Response: Systemic impact refers to conditions that affect more than one body system or the entire body.

- Post-operative condition/complication impacting recovery.

Comment: Several commenters recommended that CMS revise the language used so that this guiding principle includes the term ''post-procedure'' to more broadly recognize that some procedures also have associated complications that are severe that can typically warrant additional resources (that is, drugs, supplies, ancillary tests, etc.). These commenters stated they believed stakeholders are likely to take the wording of this guiding principle literally as originally stated. Commenters also stated that the term ''recovery'' is conceptually appropriate, so long as its use does not result in the exclusion of consideration of costs that may impact the patient stay. Another commenter also stated that CMS should describe the cost implications of each of these principles.

Response: CMS agrees that adding the term ''post-procedure'' would be appropriate to encompass procedures that have associated complications that may warrant additional resources. We are revising this guiding principle to ''post-operative/post-procedure condition/complication impacting recovery''. To clarify for the commenters, when reviewing costs, we do not analyze impact using a detailed cost accounting approach. The approach that is utilized in the mathematical analysis of claims data for impact analysis is the same expected cost approach that used in the relative weight computations. All charges in each revenue bucket, that already include supply and ancillary costs, are adjusted specific to the revenue cost to charge ratio, on a national scale and incorporated into impact values from a total estimated cost perspective. As part of this statistical review to determine if a secondary diagnosis appears to, or does not appear to, increase resource consumption, our clinical workgroup will also examine the additional days the secondary diagnosis contributed to the length of stay against what would be expected.

- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).

Comment: Commenters stated that while they agree with this principle, they request that CMS clarify if ''intermediate care'' will be considered within this guiding principle. Other

commenters requested clarification on how conditions meeting this principle would be determined. Other commenters noted that this principle is similar to Section III of the ICD–10–CM Guidelines for Coding and Reporting regarding reportable secondary diagnosis.

Response: Mathematical data regarding ICU usage will inform the clinical decision making of our internal workgroup, but we note that definitions for terms such as ''intermediate care'' and ''ICU'' vary from institution to institution. We note as stated above, our intention is not to be prescriptive in matching hospital costs, instead our intention is to ensure the severity designations appropriately reflect resource use and improve the overall accuracy of the IPPS payment system. To clarify for the commenters, the definition for ''other diagnoses'' as stated in the ICD–10–CM Official Guidelines for Coding and Reporting is intended to ensure inpatient data elements are reported in a standardized manner. This guiding principle is to intended to assist in assessing what additional resources are required for each ICD–10–CM code as a secondary diagnosis, above and beyond those that are already being utilized to address the principal diagnosis and/or other secondary diagnoses that might also be present on the claim.

• Impedes patient cooperation and/or management of care.

Comment: A number of commenters requested that codes for various social determinants of health (SDOH) be considered in this principle and in subsequent data analysis. One commenter suggested that CMS use registry information, rather than relying solely on administrative data, to take into consideration these underlying risk factors, including socioeconomic status. Another commenter questioned whether the post discharge environment should be added as a guiding principle.

Response: The ICD–10–CM classification in its entirety will be reviewed in our comprehensive CC/MCC analysis, not excluding the ICD–10–CM codes for the social determinants of health, which are the socioeconomic, cultural and environmental circumstances in which individuals live. We note the focus of our comprehensive analysis is on the appropriate severity level designation of individual ICD–10–CM codes as secondary diagnosis codes as they relate to the resource utilization required while the patient is in the hospital and on inpatient prospective payment. In reference to the comment that CMS use registry information, we appreciate the suggestion but we do not believe there is enough consistency in voluntary registry data for this purpose, and it would also be challenging for CMS to operationalize.

• Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

Comment: Many commenters stated CMS needs a method to assign CC and MCC designations to new ICD–10–CM diagnosis codes in advance of receiving claims data, since the availability of claims data lags for two years after new codes are released, to account for diagnoses which require costly treatment or might otherwise require ICU care or lengthier stays. Another commenter stated this guiding principle is poorly worded at best and vague on how it would be converted to a decision by CMS. Another commenter questioned the validity of this principle and noted that most medical conditions have potentially had some changes in best practices in the last 10 years

Response: We would like to clarify and note that CMS does have an established process to assign severity level designation to new diagnosis codes. Our process in assigning a severity level designation to a new diagnosis code generally begins with identifying the designation of the predecessor ICD–10–CM code. To inform our assignments, we also review materials from the discussions relating to proposed new diagnosis codes from the ICD–10 Coordination and Maintenance Committee meetings to determine if there are new or revised clinical concepts included in the new diagnosis codes that should also be considered when assigning a severity level designation. We refer readers to section II.E.16. of the preamble of this final rule for a discussion of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process.

We agree with the commenter that most medical conditions have potentially had some changes in best practices in the last 10 years. Significant strides have been made in the past 10 years to ensure that Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes. Consequently, we believe this comprehensive analysis should take into account the way changes in medical practice have, or have not, affected the impact on relative resource use for each ICD–10–CM code as a secondary diagnosis since our last comprehensive analysis in FY 2008.

Therefore, after consideration of the public comments we received, we are updating the nine guiding principles as follows:

• Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.

• Denotes organ system instability or failure.

• Involves a chronic illness with susceptibility to exacerbations or abrupt decline.

• Serves as a marker for advanced disease states across multiple different comorbid conditions.

• Reflects systemic impact.

• Post-operative/*post-procedure* condition/complication impacting recovery.

• Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).

• Impedes patient cooperation and/or management of care.

• Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

Comment: A few commenters recommended that CMS convene a technical advisory panel comprised of industry stakeholders and subject matter experts (including clinicians and health information professionals) to review the guiding principles. Other commenters requested that the mathematical data to be utilized in our comprehensive analysis be again presented and explained in a public listening session, similar to what the agency held in October 2019 on this topic.

Response: We again thank commenters for sharing their views and their willingness to support CMS in our efforts to continue a comprehensive CC/MCC analysis. While CMS has already convened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts, as well as provided opportunity to provide feedback on the guiding principles, we look forward to further collaboration with the industry. We plan to make an updated impact on resource use file available after publication of this final rule.

We continue to solicit feedback regarding these guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would

ensure that the severity designation appropriately reflects resource use for any diagnosis code.

Commenters should submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2020.

d. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2021

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550) we noted the following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2021 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.1—Proposed Additions to the MCC List—FY 2021;

Table 6I.2—Proposed Deletions to the MCC List—FY 2021;

Table 6J.1—Proposed Additions to the CC List—FY 2021; and

Table 6J.2—Proposed Deletions to the CC List—FY 2021.

Comment: Commenters agreed with the proposed additions and deletions to the MCC and CC lists as shown in tables 6I.1, 6I.2, 6J.1, and 6J.2 associated with the proposed rule.

Response: We appreciate the commenters' support.

As discussed in section II.E.13. of the preamble of this final rule, after consideration of the public comments received, we are finalizing changes to the severity levels for new diagnosis codes D89.833, D89.834, and D89.835 describing cytokine release syndrome (CRS) from NonCC to CC for FY 2021. Therefore, these diagnosis codes are now reflected in Table 6J.1—Additions to the CC List—FY 2021.

The following tables associated with this final rule reflect the finalized severity levels under Version 38 of the ICD–10 MS–DRGs for FY 2021 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.—Complete MCC List—FY 2021;

Table 6I.1—Additions to the MCC List—FY 2021;

Table 6I.2—Deletions to the MCC List—FY 2021;

Table 6J.—Complete CC List—FY 2021;

Table 6J.1—Additions to the CC List—FY 2021; and

Table 6J.2—Deletions to the CC List—FY 2021.

e. CC Exclusions List for FY 2021

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 37 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a non-CC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a non-CC.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550 through 32551), we discussed a request we received to consider removing diagnosis codes describing any type of stroke that is designated as a MCC in the code range I60.00 through I63.9 from the CC Exclusion list when a principal diagnosis of diabetes in the code range E08.00 through E13 is reported. According to the requestor, acute strokes and chronic diabetes are two distinct conditions, therefore a stroke that occurs during an admission for an underlying diabetic condition should not be excluded from acting as a MCC. The requestor provided an example of a patient with type 2 diabetes who was admitted for treatment of infected foot ulcers and then experienced a stroke prior to discharge, resulting in assignment to MS–DRG 639 (Diabetes without CC/MCC). The requestor asserted the more appropriate assignment is MS–DRG 637 (Diabetes with MCC), which they stated more appropriately reflects severity of illness and resources involved in the treatment of an acute stroke. In another example provided by the requestor, a patient with type 2 diabetes and osteomyelitis underwent a left below the knee amputation and experienced a stroke before discharge, resulting in assignment to MS–DRG 617 (Amputation of Lower Limb for Endocrine, Nutritional, and Metabolic Diseases with CC). The requestor asserted the more appropriate assignment is MS–DRG 616 (Amputation of Lower Limb for Endocrine, Nutritional, and Metabolic Diseases with MCC), which they stated more appropriately reflects severity of illness and resources involved in the treatment of an acute stroke.

We stated in the proposed rule that our clinical advisors agreed that acute strokes and chronic diabetes are two distinct conditions and a case reporting a secondary diagnosis of a stroke in the code range I60.00 through I63.9 should not be excluded from acting as a MCC when reported with a principal diagnosis of diabetes in the code range E08.00 through E13.9.

As noted in the proposed rule, we analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting a principal diagnosis of diabetes in the code range E08.00 through E13.9 with a secondary diagnosis of a stroke in the code range I60.00 through I63.9. We refer the reader to table 6P.3a for a detailed list of the diagnosis codes describing diabetes that were analyzed and table 6P.3b associated with the proposed rule for a detailed list of the diagnosis codes describing a stroke that were analyzed and that are also designated as a MCC in this code range. We found a total of 1,109 cases across 40 MS–DRGs with an average length of stay of 10.1 days and average costs of $24,672 reporting a principal diagnosis of diabetes with a secondary diagnosis of a stroke that was excluded from acting as a MCC. Of those 1,109 cases, we identified 161 cases that would result in assignment to the higher severity level ''with MCC'' MS–DRG if the diagnosis of stroke was no longer excluded from acting as a MCC. The remaining 948 cases would maintain their existing MS–DRG assignment since they were either already grouped to the highest MCC severity level based on another diagnosis code that is designated as a MCC or they were assigned to one of the Pre-MDC MS–DRGs. We refer the reader to table 6P.4a associated with the proposed rule for the detailed analysis.

Based on the advice of our clinical advisors, for FY 2021, we proposed to remove the diagnosis codes describing stroke in the code range I60.00 through I63.9 that are designated as a MCC from the list of CC Exclusions when reported with a principal diagnosis of diabetes in the code range E08.00 through E13.9 from the ICD–10 MS–DRGs Version 38 CC Exclusion List as reflected in Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2021 and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021 associated with the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.*

Comment: Commenters supported the proposal to remove diagnosis codes describing stroke in the code range I60.00 through I63.9 that are designated as a MCC from the list of CC Exclusions when reported with a principal diagnosis of diabetes in the code range E08.00 through E13.9.

Response: We thank the commenters for their support.

We proposed additional changes to the ICD–10 MS–DRGs Version 38 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.D.13. of the FY 2021 IPPS/LTCH PPS proposed rule and set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.*

Comment: Commenters supported the proposed additions and deletions to the CC Exclusion List as shown in tables 6G.1, 6G.2, 6H.1 and 6H.2.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove diagnosis codes describing stroke in the code range I60.00 through I63.9 that are designated as a MCC from the list of CC Exclusions when reported with a principal diagnosis of diabetes in the code range E08.00 through E13.9.

The proposed CC Exclusions for a subset of the diagnosis codes as set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the FY 2021 IPPS/LTCH PPS proposed rule reflect the proposed severity level designations as discussed in section II.D.13. of the preamble of the proposed rule. As discussed in section II.E.13. of the preamble of this final rule, we are finalizing changes to the severity level designations for three diagnosis codes after consideration of the public comments received. Therefore, the finalized CC Exclusions List as displayed in Tables 6G.1, 6G.2, 6H.1 6H.2, and 6K, associated with this final rule reflect the severity levels under Version 38 of the ICD–10 MS–DRGs.

We have developed Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2021; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2021; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2021; Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021; and Table 6K.—Complete List of CC Exclusions—FY 2021. For Table 6G.1, each secondary diagnosis code for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Table 6K is a list of all of the codes that are defined as either CC or a MCC when used as a secondary diagnosis. Within the table each code is specifically indicated as CC or MCC. A table number is given to a collection of diagnosis codes which, when used as the principal diagnosis, will cause the CC or MCC to be considered as only a non-CC. Tables 6G.1., 6G.2., 6H.1., 6H.2., and 6K. associated with this final rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

The ICD–10 MS–DRGs Version 38 CC Exclusion List is included as Appendix C of the Definitions Manual (available in two formats; text and HTML). The manuals are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* and each format includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link (HTML version) is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a non-CC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a non-CC.

13. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2021, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, and Table 6E.—Revised Diagnosis Code Titles for this final rule.

These tables are not published in the Addendum to the proposed rule or final rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/AcuteInpatientPPS/index.html as described in section VI. of the Addendum to this final rule. As discussed in section II.E.16. of the preamble of this final rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32551 through 32552), we proposed the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. We also stated that the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B.

Comment: A commenter stated they appreciated the finalization of new ICD–10–CM diagnosis code J84.170 (Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere) that was included in Table 6A—New Diagnosis Codes associated with the proposed rule. The commenter stated this new diagnosis code will provide clarification for current coding of Interstitial Lung Disease (ILD) within the ICD–10–CM classification by enabling identification of patients with chronic fibrotic ILD who exhibit a progressive phenotype. The commenter noted this update is critical for facilitating research for patients with a progressive fibrotic ILD phenotype which is an area of high unmet needs. Another commenter also supported the creation of diagnosis code J84.170 and stated they generally support new ICD–10 codes that enable identification of beneficiaries with specific diseases or clinically important diagnoses, such as that represented by diagnosis code J84.170. However, the commenter expressed concern that the process for obtaining new ICD–10 codes can be cumbersome and cause delays in approving new codes that are important to identify and support appropriate treatment for patients with specific diseases or conditions. The commenter provided an example that current ICD–10 codes do not accurately characterize the disease progression of Alzheimer's Disease and have not kept up with the current clinical documentation and management of patient treatments, and do not accurately reflect the various stages of disease progression. The commenter noted that proper identification is necessary, not only in clinical practice, but also to track the real word outcomes as patients progress through the disease states. The commenter stated CMS, along with the CDC, should consider steps to expedite the timetable for implementing important new diagnosis codes in emerging therapeutic areas in order to ensure timely patient access to vital treatment options.

Response: We appreciate the commenters' support. In response to the commenter who expressed concern regarding the process and timing for obtaining new ICD–10 codes, we note that, as discussed in section II.E.16. of the preamble of this final rule, the CDC/NCHS has lead responsibility for the ICD–10–CM diagnosis classification while CMS has lead responsibility for the ICD–10–PCS procedure classification. Each organization has their own established process in responding to requests for code updates, including when specific topics may appear on the agenda of an ICD–10 Coordination and Maintenance Committee meeting and the fiscal year in which code proposals are considered for implementation. With regard to the commenter's concerns involving outdated and insufficient diagnosis code descriptions for Alzheimer's Disease, we encourage the commenter to contact the CDC/NCHS directly as they have lead responsibility for the ICD–10–CM diagnosis classification. Requests for new and revised diagnosis code updates must be submitted to *nchsicd10cm@cdc.gov* for consideration. In response to the commenter's suggestion that CMS and CDC should consider steps to expedite the timetable for implementing important new diagnosis codes in emerging therapeutic areas in order to ensure timely patient access to vital treatment options, we note that, as also discussed in section II.E.16. of the preamble of this final rule, there are existing processes in place to implement diagnosis codes in an expedited manner.

Comment: A commenter expressed appreciation for CMS' request for comment on the MDC, MS–DRG and severity level for diagnosis code U07.1 (COVID–19). The commenter stated there are variable and changing practices related to COVID–19, particularly as related to medication use. In addition, the commenter noted as medications may be used off-label or become newly approved for COVID–19, the cost of those medications remains to be seen. According to the commenter, these costs may have a significant impact on a hospital's ability to treat patients with COVID–19. Therefore, the commenter suggested that as CMS considers the most appropriate MDC, MS–DRG and severity level assignments for diagnosis code U07.1, it recommended the agency account for the ongoing changes in best practices and medication use related to COVID–19, and whether additional reimbursement options or flexibilities could be provided to limit financial risks to hospitals. Another commenter applauded the speed with which CMS and CDC/NCHS addressed and implemented the new ICD–10–CM diagnosis codes U07.0 (Vaping-related disorder) and U07.1 (COVID–19) effective April 1, 2020 with MS–DRG assignments. This commenter encouraged the agencies to respond swiftly to address any similar public health emergencies in the future.

Response: We thank the commenters for their support. In Table 6A—New Diagnosis Codes, associated with the proposed rule, we proposed to continue to designate diagnosis code U07.1 (COVID–19) as a MCC in MDC 04 (Diseases and Disorders of the Respiratory System) for MS–DRGs 177, 178, and 179 (Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively); in MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period) for MS–DRGs 791 (Prematurity with Major Problems) and 793 (Full Term Neonate with Major Problems); and in MDC 25 (Human Immunodeficiency Virus Infections) for MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively). We note that these are the same MDC and MS–DRG assignments that were applied at the time diagnosis code U07.1 was implemented, effective April 1, 2020, as discussed in section II.D.16. of the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32559). In response to the commenter's recommendation that CMS account for changes in best practices and medications used for the treatment of COVID–19 with respect to providing additional payment options and flexibilities to limit financial risk to hospitals, we note that we have developed several resources in the form of a Coronavirus (COVID–19) Partner Toolkit available at the following CMS webpage: *https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit* for various providers with respect to the COVID–19 public health emergency. Specifically, on that CMS webpage under the section titled ''If you are in a Care Setting'' there is a ''Hospitals and

Healthcare Systems'' list of 20 resource documents that have been made publicly available.

Comment: Several commenters expressed concern regarding the proposed NonCC severity level designation for a subset of the new ICD–10–CM diagnosis codes describing cytokine release syndrome (CRS) as displayed in Table 6A—New Diagnosis Codes (associated with the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). Specifically, the commenters stated diagnosis codes D89.833 (Cytokine release syndrome, grade 3), D89.834 (Cytokine release syndrome, grade 4), and D89.835 (Cytokine release syndrome, grade 5) warrant further consideration. The commenters noted that CRS has emerged as an established diagnosis in association with CAR T-cell therapy for various cancers, and providers are now seeing this syndrome in patients who present with COVID–19. The commenters requested CMS reconsider how the diagnosis codes describing CRS are designated within the ICD–10 MS–DRGs.

Some commenters suggested that the American Society for Transplantation and Cellular Therapy (ASTCT) CRS Grading system be examined in review of potential CC and MCC designations for the CRS diagnosis codes. Other commenters stated that based on the ASTCT CRS Grading system, the CRS diagnosis codes describing grades 3, 4, and 5 appear to satisfy many of the CMS guiding principles discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550). A commenter recommended that severity level assignments for the various grades of CRS could be used as a test case for these new guiding principles. According to the commenter, the guiding principles as described in the proposed rule do not indicate that a required threshold for the number of cases for Medicare patients be attained before an analysis of the severity level assignment occurs. The commenter stated that based on the ASTCT CRS Grading system, grades 3, 4 and 5 meet the criteria for 7 of the 9 proposed guiding principles. The commenter provided the following information for CMS' consideration.

Guiding Principle	CRS Code
1. Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility	CRS Grades 4 and 5
2. Denotes organ system instability or failure	CRS Grades 3, 4 and 5
3. Involves a chronic illness with susceptibility to exacerbations or abrupt decline	
4. Serves as a marker for advanced disease states across multiple different comorbid conditions	
5. Reflects systemic impact	CRS Grades 3, 4 and 5
6. Post-operative condition/complication impacting recovery	CRS Grades 3, 4 and 5
7. Typically requires higher level of care	CRS Grades 3, 4 and 5
8. Impedes patient cooperation and/or management	CRS Grades 3, 4 and 5
9. Recent (last 10 years) change in best practice, or in practicing guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use	CRS Grades 3, 4 and 5

This same commenter also suggested that CMS consider expanding the logic for the CRS diagnosis codes to include patients diagnosed with COVID–19. The commenter reported that based on current academic literature, CRS is a common occurrence and a focus of treatment in patients presenting with advanced COVID–19. According to the commenter, the presence of CRS in the COVID–19 population also indicates that the new CRS diagnosis codes meet the 4th guiding principle of ''marker for advanced disease states across multiple different comorbid conditions.''

Another commenter urged CMS to assign the CRS diagnosis codes identified as Grades 3, 4, and 5 (D89.833, D89.834, and D89.835, respectively) as a MCC and to assign the CRS diagnosis code identified as Grade 2, D89.832 (Cytokine release syndrome, grade 2) as a CC based on clinical significance. The commenter agreed with the proposed NonCC designation for the CRS diagnosis code identified as Grade 1, D89.831 (Cytokine release syndrome, grade 1) until additional data is available for analysis and consideration.

A commenter noted that for Table 6A—New Diagnosis Codes, associated with the proposed rule, that the proposed MDC for the new CRS diagnosis codes is MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders) and the proposed MS–DRGs are 814, 815, and 816 (Reticuloendothelial and Immunity Disorders with MCC, with CC, and without CC/MCC, respectively). The commenter stated that since the CRS diagnosis codes were proposed as NonCC it understood this to equate to the CRS diagnosis codes being assigned to MS–DRG 816. The commenter disagreed with the proposed severity levels for the CRS diagnosis codes and recommended CMS consider revising. According to the commenter, CRS is the most common complication of Immune Effector Cell (IEC) therapy as described in the ASTCT's Consensus Grading

paper.[1] Symptoms can be progressive, include fever at the onset, and may include hypotension, hypoxia, and end organ dysfunction. The commenter noted that patients with CRS grade 3 require treatment for hypotension and hypoxia and patients with CRS grade 4 experience hypoxia requiring treatment, are hemodynamically unstable, and have capillary leak which can lead to pulmonary edema and ventilation impairment and may require mechanical ventilation. Lastly, the commenter noted CRS grade 5 is defined as ''death due to CRS,'' and suggested this condition be considered a MCC. In addition, the commenter compared the APR–DRG Grouper severity levels, as described in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47158) to inform how CMS should assign CC/MCC designations for the new CRS codes. For example, the commenter suggested diagnosis code D89.831 (Cytokine release syndrome, grade (1) should be designated as NonCC; diagnosis code D86.832 (Cytokine release syndrome, grade (2) should be designated as CC; diagnosis code D89.833 (Cytokine release syndrome, grade (3) should be designated as MCC; diagnosis code D89.834 (Cytokine release syndrome, grade (4) should be designated as MCC; diagnosis code D89.835 (Cytokine release syndrome, grade (5) should be designated as MCC; and diagnosis code D89.839 (Cytokine release syndrome, grade unspecified) should be designated as NonCC.

Similar to comments discussed earlier in this section, this commenter also stated that when applying CMS' guiding principles as described in the proposed rule for severity level assignments, many of them are applicable to the new CRS diagnosis codes. The commenter provided the following table for CMS' consideration and review which also included recommended MS–DRG assignments.

Name/Description of Principle	Diagnosis Code	CRS Grade	CC/MCC Status	Recommended MS-DRG Assignment
Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)
Denotes organ system instability or failure.	D89.832	2	CC	815 (CC MS-DRG)
	D89.833	3	MCC	814 (MCC MS-DRG)
	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)
Reflects systemic impact.	D89.833	3	MCC	814 (MCC MS-DRG)
	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)
	D89.832	2	CC	815 (CC MS-DRG)

[1] ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. Lee, Daniel W. et al. Biology of Blood and Marrow Transplantation, Volume 25, Issue 4, 625–638.

Name/Description of Principle	Diagnosis Code	CRS Grade	CC/MCC Status	Recommended MS-DRG Assignment
Post-operative condition/complication impacting recovery.	D89.833	3	MCC	814 (MCC MS-DRG)
	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)
Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).	D89.832	2	CC	815 (CC MS-DRG)
	D89.833	3	MCC	814 (MCC MS-DRG)
	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)
Impedes patient cooperation and/or management of care.	D89.833	3	MCC	814 (MCC MS-DRG)
	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)
Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.	D89.833	3	MCC	814 (MCC MS-DRG)
	D89.834	4	MCC	814 (MCC MS-DRG)
	D89.835	5	MCC	814 (MCC MS-DRG)

The commenter also noted that coding guidelines instruct the CRS diagnosis codes to be sequenced as a secondary diagnosis with a complication code (T code) sequenced first when CRS is a complication due to a procedure. The commenter expressed concern regarding how CRS cases will group into MS–DRGs 814, 815, and 816 as proposed by CMS since sequencing a T code as the principal diagnosis results in a different MS–DRG assignment. The commenter suggested CMS consider revising the Grouper logic, proposing different MS–DRGs for CRS and allow for public comment, or urging NCHS to change the coding instruction at subcategory D89.83 to allow only for diagnosis code T80.90XA (Unspecified complication following infusion and therapeutic injection) to be reported first since it would group to MS–DRGs 814, 815, and 816. The commenter also urged CMS to request that the NCHS and the AHA publish clear coding guidance to eliminate any confusion about the appropriate T code to report for CRS due to CAR T-cell therapy.

Another commenter also recommended that CMS assign the new CRS diagnosis codes to CC and MCC MS–DRGs within the MS–DRG 814, 815, and 816 series. The commenter stated their belief that several of the CMS guiding principles described in the proposed rule provide sufficient rationale for such assignments. The commenter also stated that once information regarding the CRS codes becomes available in the claims data, CMS can re-evaluate MS–DRG assignments.

Response: Consistent with our annual process of assigning new diagnosis codes to MDCs, MS–DRGs, and designating a severity level (MCC, CC or NonCC), we reviewed the predecessor diagnosis code assignment for CRS. The predecessor code for CRS is diagnosis code D89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified) which is designated as a NonCC, therefore our proposed severity level designation for each of the CRS codes was also a NonCC. After consideration of the commenters' concerns regarding the proposed severity level designations for the new ICD–10–CM diagnosis codes describing cytokine release syndrome (hereafter referred to as ''CRS codes'') as displayed in Table 6A—New Diagnosis Codes, associated with proposed rule, we agree that the CRS codes warrant further consideration.

Upon further review and consideration, our clinical advisors believe a CC severity level for CRS codes identified as grade 3, 4, or 5 would be warranted since these patients may require additional resources and treatment including intensive monitoring, blood pressure support, oxygen or mechanical ventilation, that are above and beyond the resources required for patients with CRS identified as a grade 1, 2, or an unspecified grade. Our clinical advisors continue to believe that CRS codes with a grade 1, 2, or an unspecified grade do not warrant the CC severity level.

Our clinical advisors also acknowledged the commenters' recommendations to review the American Society for Transplantation and Cellular Therapy (ASTCT) CRS Grading system to reassess potential CC and MCC designations for the CRS codes and consider how the CMS guiding principles discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550) could be applied as a test case for the various grades of the CRS codes. As noted previously, we applied our established process in proposing severity level assignments for these codes and the other new diagnosis codes for FY 2021. We also note that the guiding principles continue to be under development as we consider the public comments received, as discussed in section II.E.12.c. of the preamble of this final rule. We further note that with respect to proposing severity level assignments for new diagnosis codes in the future, we anticipate continuing our current process of first reviewing the predecessor code assignment, followed by review and consideration of the guiding principles that may be applied, in future rulemaking.

We note that while our clinical advisors do not dispute the commenters' assessments that the CRS codes would appear to meet most of the guiding principles, they also noted, as discussed previously, that a distinction between

assigning the codes as a CC versus a MCC cannot be made based on the fact that they appear to meet several of the guiding principles nor can assignment of a secondary diagnosis be based on whether the code meets 1 or 2 principles or meets 7 or 8 of the principles. Our clinical advisors maintain that generally, the proposed severity level ultimately depends on clinical judgement and, where the data is available, the empirical analysis of the additional resources associated with the secondary diagnosis. The impact of the secondary diagnosis is dependent on the principal diagnosis reported, with which it is associated. If the secondary diagnosis is reported primarily with a principal diagnosis that reflects serious illness with treatment complexity, then the marginal contribution of the secondary diagnosis to the overall resource use may actually be relatively small. The CRS codes initially appeared to fall into this category, since it occurs in patients who are quite ill to begin with, the ''grading'' definitions have varied among organizations, and it has evolved over time. However, for the reasons noted, and after further consideration, we believe that a CC severity level for CRS codes identified as grade 3, 4, or 5 is warranted. We will continue to monitor the CRS codes and their impact on resource use once the claims data becomes available to determine if further modifications to the severity level are warranted.

In response to the commenter who expressed concern regarding how CRS cases will group into MS–DRGs 814, 815, and 816 as proposed by CMS (since sequencing certain T codes as the principal diagnosis results in a different MS–DRG assignment), we note that after notification and consideration of the concerns involving the proposed Tabular List instructions for the CRS codes were brought to its attention, the CDC/NCHS updated and finalized the Tabular instruction for the CRS codes. As noted in section II.E.16. of the preamble of this final rule, the CDC/NCHS has lead responsibility for the diagnosis codes and CMS has lead responsibility for the ICD–10–PCS procedure codes. The finalized changes effective FY 2021 include updates to the diagnosis codes instructed to be sequenced first, followed by the applicable CRS code as follows:

D89.83 Cytokine release syndrome

Code first underlying cause, such as:

Complications following infusion, transfusion and therapeutic injection (T80.89-)

complications of transplanted organs and tissue (T86.-)

Use additional code to identify associated manifestations

D89.831 Cytokine release syndrome, grade 1

D89.832 Cytokine release syndrome, grade 2

D89.833 Cytokine release syndrome, grade 3

D89.834 Cytokine release syndrome, grade 4

D89.835 Cytokine release syndrome, grade 5

D89.839 Cytokine release syndrome, grade unspecified

As a result, CMS considered modifications to the GROUPER logic to allow cases reporting diagnosis code T80.89XA (Other complications following infusion, transfusion and therapeutic injection) as the principal diagnosis with any one of the CRS codes as a secondary diagnosis to group to MS–DRGs 814, 815, and 816. We note that diagnosis code T80.90XA (Unspecified complication following infusion and therapeutic injection) as the commenter suggested would not be appropriate to report as the principal diagnosis for these cases since the code descriptor refers to an ''unspecified complication'' and the complication is specified as CRS. In response to the commenter's suggestion that CMS request the NCHS and the AHA publish clear coding guidance to eliminate any confusion about the appropriate T code to report for CRS due to CAR T-cell therapy, we note that it is standard practice for the AHA to publish coding guidance for the annual diagnosis and procedure code updates in the AHA's *Coding Clinic for ICD–10–CM and ICD–10–PCS* 4th Quarter publication each year.

With respect to the commenter who recommended that CMS assign the new CRS diagnosis codes to CC and MCC MS–DRGs within the MS–DRG 814, 815, and 816 series, we note that whenever there are new diagnosis codes finalized, the first step for incorporating the new diagnosis code into the logic of the ICD–10 MS–DRGs is to assign the diagnosis code to the appropriate MDC. The next step is to determine if and how the diagnosis code may define the logic for a specific MS–DRG assignment. For example, the diagnosis may be listed as principal or as any one of the secondary diagnoses, as a secondary diagnosis, or only as a secondary diagnosis as noted in more detail below.

- Principal or secondary diagnoses. Indicates that a specific set of diagnoses are used in the definition of the MS–DRG. The diagnoses may be listed as principal or as any one of the secondary diagnoses. A special case of this condition is MS–DRG 008 in which two diagnoses (for example, renal and diabetic) must both be present somewhere in the list of diagnoses in order to be assigned to MS–DRG 008.
- Secondary diagnoses. Indicates that a specific set of secondary diagnoses are used in the definition of the MS–DRG. For example, a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839.
- Only secondary diagnoses. Indicates that in order to be assigned to the specified MS–DRG no secondary diagnoses other than those in the specified list may appear on the patient's record. For example, in order to be assigned to MS–DRG 795, only secondary diagnoses from the specified list may appear on the patient's record.

As discussed earlier in this section, modifications to the GROUPER logic were made to allow cases reporting diagnosis code T80.89XA (Other complications following infusion, transfusion and therapeutic injection) as the principal diagnosis with any one of the CRS codes as a secondary diagnosis to group to MS–DRGs 814, 815, and 816. We note that whenever there is a secondary diagnosis component to the MS–DRG logic, the diagnosis code can either be used in the logic for assignment to the MS–DRG or to act as a CC/MCC. For this specific scenario, the CRS codes, as secondary diagnoses, are being used in the definition of the logic for assignment to MS–DRGs 814, 815, and 816, similar to the example described above, where a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839.

In response to the commenter that suggested CMS consider expanding the logic for the CRS diagnosis codes to include patients diagnosed with COVID–19, we note that for cases where CRS is present in a patient diagnosed with COVID–19, depending on the circumstances of the admission, the COVID–19 would be reported as the principal diagnosis and the appropriate CRS code would be reported as a secondary diagnosis. In this scenario, the case would group to a MS–DRG under MDC 04 (Diseases and Disorders of the Respiratory System) because that is where diagnosis code U07.1, (COVID–19) is assigned. Therefore, we do not agree that it is necessary to create specific logic for these patients.

After consideration of the public comments received, and for the reasons previously discussed, for FY 2021, we are modifying our proposed severity level designations for a subset of the CRS codes as shown in Table 6A—New Diagnosis Codes, associated with this

final rule, and displayed in the table below.

ICD-10-CM Code	Description	Proposed Severity Level	Finalized Severity Level
D89.831	Cytokine release syndrome, grade 1	NonCC	NonCC
D89.832	Cytokine release syndrome, grade 2	NonCC	NonCC
D89.833	Cytokine release syndrome, grade 3	NonCC	CC
D89.834	Cytokine release syndrome, grade 4	NonCC	CC
D89.835	Cytokine release syndrome, grade 5	NonCC	CC
D89.839	Cytokine release syndrome, grade unspecified	NonCC	NonCC

We are also finalizing modifications to the ICD–10 MS–DRG GROUPER logic V38 for MS–DRGs 814, 815, and 816. Effective with discharges on and after October 1, 2020 (FY 2021), the logic for case assignment to MS–DRGs 814, 815, and 816 will include a principal diagnosis of T89.89XA with a secondary diagnosis of any CRS code as noted below.

Principal Diagnosis

T80.89XA Other complications following infusion, transfusion and therapeutic injection, initial encounter

with

Secondary Diagnosis

D89.831 Cytokine release syndrome, grade 1
D89.832 Cytokine release syndrome, grade 2
D89.833 Cytokine release syndrome, grade 3
D89.834 Cytokine release syndrome, grade 4
D89.835 Cytokine release syndrome, grade 5
D89.839 Cytokine release syndrome, grade unspecified

Comment: Several commenters requested that CMS consider higher reimbursement for the performance of ultrasound accelerated thrombolysis procedures utilizing the EKOS™ device. Specifically, the commenters recommended that ultrasound accelerated thrombolysis procedures performed with the EKOS™ device for the treatment of pulmonary embolism (PE) should be assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) versus MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), and ultrasound accelerated thrombolysis procedures performed with the EKOS™ device for the treatment of deep venous thrombosis (DVT) should be assigned to MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) versus MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively), as proposed in Table 6B—New Procedure Codes associated with the proposed rule, regardless of a physician's clinical decision to use a device that removes matter or a device that fragments matter using ultrasound accelerated thrombolysis. Some commenters asserted that unique devices that remove matter, known as extirpating devices, are very similar to the EKOS™ device in the performance of an ultrasound accelerated thrombolysis procedure to treat PE or DVT. The commenters stated the difference is that these extirpating devices, specifically the FlowTriever® and ClotTriever® (Inari Medical, Inc) and the Indigo® System (Penumbra), remove matter and the EKOS™ device (Boston Scientific), fragments matter with the use of thrombolytics and ultrasonic assistance.

A commenter stated its belief that:

A. Percutaneous ultrasonic fragmentation and extirpation are both catheter-based procedures that address solid matter in a body part;

B. Percutaneous ultrasonic fragmentation is similar to other procedures in the requested MS–DRGs;

C. Both fragmentation and extirpation procedures were evaluated using similar PE pivotal trial designs and have similar efficacy results;

D. Both types of procedures have similar overall hospital resource utilization;

E. Medicare cost data do not reflect EKOS™ cost; and

F. Medicare precedent exists for assignment of new codes to higher paying groups.

Below we provide the commenters' summaries for each of the statements listed above which also reflect similar statements or sentiments submitted by several of the other commenters.

A. Percutaneous Ultrasonic Fragmentation and Extirpation are Both Catheter-Based Procedures That Address Solid Matter in a Body Part

According to the commenter, clot reduction using percutaneous ultrasonic fragmentation is similar to extirpation in many respects. The commenter stated these technologies all use percutaneous approaches, all treat serious PE, all reduce thrombus burden and all treat patients in the inpatient hospital setting with intensive care unit (ICU) care. The commenter provided the following table for comparison of the different technologies.

Pulmonary Embolism (PE) Percutaneous Clot Reduction Procedure Comparison			
	EKOS™ Boston Scientific	**FlowTriever®** Inari Medical	**Indigo® System** Penumbra
Percutaneous Approach	X	X	X
Treat Serious PE	X	X	X
Reduce Thrombus Burden	X	X	X
Inpatient Hospital with ICU	X	X	X
MS-DRGs	166-168	163-165	163-165

The commenter stated that similarly, procedures using percutaneous clot reduction devices for peripheral vascular (PV) procedures exhibit many key similarities. All use percutaneous approaches, all manage PV thromboemboli, all reduce thrombus burden, and all involve inpatient hospital admission with ICU care. The commenter provided the following table for comparison.

Peripheral Vascular (PV) Percutaneous Clot Reduction Procedure Comparison				
	EKOS™ Boston Scientific	**ClotTriever®** Inari Medical	**AngioJet™** Boston Scientific	**Indigo® System** Penumbra
Percutaneous Approach	X	X	X	X
Manage PV Thromboemboli	X	X	X	X
Reduce Thrombus Burden	X	X	X	X
Inpatient Hospital with ICU	X	X	X	X
MS-DRGs	252-254	270-272	270-272	270-272

B. Percutaneous Ultrasonic Fragmentation Is Similar to Procedures in the Requested MS–DRGs

According to the commenter, for PE, percutaneous ultrasonic fragmentation procedures are clinically similar to procedures that are assigned to MS–DRGs 163, 164, and 165. The commenter stated that both extirpation codes and percutaneous ultrasonic fragmentation codes are reporting services that are intended to reduce clot burden, addressing matter in the body. The commenter provided the following list of procedure codes describing extirpation of matter from pulmonary structures that are currently assigned to MS–DRGs 163, 164, and 165 that it stated are clinically similar to percutaneous ultrasonic fragmentation procedures for PE.

Percutaneous Extirpation Procedures of Pulmonary Structures in MS-DRGs 163, 164, and 165	
ICD-10-PCS Code	**Code Description**
02CP3ZZ	Extirpation of matter from pulmonary trunk, percutaneous approach
02CQ3ZZ	Extirpation of matter from right pulmonary artery, percutaneous approach
02CR3ZZ	Extirpation of matter from left pulmonary artery, percutaneous approach
02CS3ZZ	Extirpation of matter from right pulmonary vein, percutaneous approach
02CT3ZZ	Extirpation of matter from left pulmonary vein, percutaneous approach

Alternatively, the commenter stated that PE percutaneous ultrasonic fragmentation procedures are not clinically similar to other procedures assigned to MS–DRGs 166, 167, and 168. According to the commenter, percutaneous ultrasonic fragmentation is unlike the other percutaneous procedure codes assigned to these MS–DRGs and even opposite to some. The commenter noted an example of how occlusion procedures stop flow, while percutaneous ultrasonic fragmentation restore flow. The commenter provided the following list of procedure codes describing occlusion and repair of pulmonary structures that are currently assigned to MS–DRGs 166, 167, and 168 that it stated are not clinically similar to percutaneous ultrasonic fragmentation procedures for a PE.

Percutaneous Occlusion and Repair Procedures of Pulmonary Structures in MS-DRGs 166, 167, and 168	
ICD-10-PCS Code	**Code Description**
02LP3CZ	Occlusion of pulmonary trunk with extraluminal device, percutaneous approach
02LP3DZ	Occlusion of pulmonary trunk with intraluminal device, percutaneous approach
02LP3ZZ	Occlusion of pulmonary trunk, percutaneous approach
02LQ3CZ	Occlusion of right pulmonary artery with extraluminal device, percutaneous approach
02LQ3DZ	Occlusion of right pulmonary artery with intraluminal device, percutaneous approach
02LQ3ZZ	Occlusion of right pulmonary artery, percutaneous approach
02LR3CZ	Occlusion of left pulmonary artery with extraluminal device, percutaneous approach
02LR3DZ	Occlusion of left pulmonary artery with intraluminal device, percutaneous approach
02LR3ZZ	Occlusion of left pulmonary artery, percutaneous approach
02QP3ZZ	Repair pulmonary trunk, percutaneous approach
02QQ3ZZ	Repair right pulmonary artery, percutaneous approach

In addition, the commenter stated that for PV procedures, percutaneous ultrasonic fragmentation procedures are clinically similar to procedures in MS–DRGs 270, 271, and 272. The commenter reiterated that both extirpation codes and fragmentation codes identify services that are intended to reduce clot burden, addressing matter in the body. The commenter provided the following list of procedure codes describing extirpation of matter from PV structures that are currently assigned to MS–DRGs 270, 271, and 272 it stated are clinically similar to percutaneous ultrasonic fragmentation procedures for PE.

Percutaneous Extirpation Procedures of Peripheral Vascular (PV) Structures in MS-DRGs 270, 271, and 272	
ICD-10-PCS Code	**Code Description**
06CC3ZZ	Extirpation of matter from right common iliac vein, percutaneous approach
06CD3ZZ	Extirpation of matter from left common iliac vein, percutaneous approach
06CF3ZZ	Extirpation of matter from right external iliac vein, percutaneous approach
06CG3ZZ	Extirpation of matter from left external iliac vein, percutaneous approach
06CM3ZZ	Extirpation of matter from right femoral vein, percutaneous approach

According to the commenter, as it noted with PE, percutaneous ultrasonic fragmentation PV procedures are generally unlike the codes and even opposite to some of the other ICD–10–PCS procedures in MS–DRGs 252, 253, and 254. For example, the commenter stated that percutaneous ultrasonic fragmentation is not comparable to dilation, which is the root operation for balloon angioplasty or vascular stenting and is primarily used to address peripheral artery disease, a condition which is very different than thrombotic events. The commenter reported that percutaneous ultrasonic fragmentation procedures using the EKOS™ device typically involve leaving the EKOS™ device in the body for multiple hours and in many cases overnight, which allows time for the thrombolytic to break apart the thrombus with ultrasonic assistance. The commenter noted the duration of angioplasty or stenting procedures are typically measured in minutes, rather than in hours. The commenter also noted that percutaneous ultrasonic fragmentation procedures are not similar to release procedures such as a carpal tunnel release procedure, which usually takes around ten minutes and involves cutting the carpal ligament. Conversely, percutaneous ultrasonic fragmentation catheters typically remain in the patient's body for multiple hours or

overnight and do not cut ligaments, according to the commenter. The commenter provided the following list of procedure codes describing dilation (angioplasty) and release of PV structures that are currently assigned to MS–DRGs 252, 253, and 254 that it stated are not clinically similar to percutaneous ultrasonic fragmentation procedures for a PV procedure.

Percutaneous Dilation and Release Procedures of Peripheral Vascular (PV) Structures in MS-DRGs 252, 253, and 254	
ICD-10-PCS Code	**Code Description**
067M3DZ	Dilation of right femoral vein with intraluminal device, percutaneous approach
067M3ZZ	Dilation of right femoral vein, percutaneous approach
067N3DZ	Dilation of left femoral vein with intraluminal device, percutaneous approach
067N3ZZ	Dilation of left femoral vein, percutaneous approach
06NM3ZZ	Release right femoral vein, percutaneous approach
06NN3ZZ	Release left femoral vein, percutaneous approach
067M3DZ	Dilation of right femoral vein with intraluminal device, percutaneous approach
067M3ZZ	Dilation of right femoral vein, percutaneous approach

067N3DZ	Dilation of left femoral vein with intraluminal device, percutaneous approach
067N3ZZ	Dilation of left femoral vein, percutaneous approach
06NM3ZZ	Release right femoral vein, percutaneous approach
06NN3ZZ	Release left femoral vein, percutaneous approach
067C3DZ	Dilation of right common iliac vein with intraluminal device, percutaneous
067C3ZZ	Dilation of right common iliac vein, percutaneous approach
067D3DZ	Dilation of left common iliac vein with intraluminal device, percutaneous
067D3ZZ	Dilation of left common iliac vein, percutaneous approach
067F3DZ	Dilation of right external iliac vein with intraluminal device, percutaneous
067F3ZZ	Dilation of right external iliac vein, percutaneous approach
067G3DZ	Dilation of left external iliac vein with intraluminal device, percutaneous
067G3ZZ	Dilation of left external iliac vein, percutaneous approach

C. Similar PE Pivotal Trial Designs and Efficacy Results

The commenter stated that pivotal clinical studies for the treatment of PE with percutaneous ultrasonic fragmentation using EKOS™ and for extirpation using comparable devices are consistent, with all designed using the same primary outcome measure. According to the commenter, the design of pivotal studies for the extirpating devices (FLARE and EXTRACT–PE) closely mirrors that of the EKOS™ PE study, SEATTLE II. The commenter provided a table of device comparisons that were used in the three pivotal clinical trials to assess treatment of PE followed by another table to illustrate its findings.

The commenter stated that the FLARE and EXTRACT–PE trials have nearly identical primary outcome measures and comparable results to that of the EKOS™ device SEATTLE II study, further validating the clinical similarity between the EKOS™ device and the comparable extirpating devices. According to the commenter, mirroring the EKOS™ SEATTLE II study design validates comparability of patients and procedures. The commenter asserted that percutaneous ultrasonic fragmentation procedures with the EKOS™ device have comparable, and in some cases even greater, use of hospital resources than extirpation procedures, with a longer length of stay in the SEATTLE II study than extirpation procedures in the FLARE study, with multi-day confidence intervals.

D. Similar Hospital Resource Utilization

The commenter stated that the SEATTLE II pivotal trial demonstrated an average length of stay of 8.8 ± 5 days for percutaneous ultrasonic fragmentation procedures with the EKOS™ device and the FLARE pivotal trial showed the hospital average length of stay of 4.1 ± 3.5 days for the FlowTriever® device. The commenter also stated that an analysis of MedPAR

claims for extirpating PE admissions showed a geometric mean length of stay similar to the FLARE study, with length of stay ranging from 2.9 to 5.1 days across MS–DRGs 163, 164 and 165. The commenter further stated that from a hospital resource utilization perspective, the SEATTLE II trial demonstrated that percutaneous ultrasonic fragmentation procedures with the EKOS™ device involved a length of stay greater than or equal to that of the comparable extirpation procedures performed with extirpation devices, given multi-day confidence intervals. The commenter provided a table to illustrate its findings of extirpation procedures performed for PE across MS–DRGs 163, 164, and 165.

The commenter also reported that the cost of the percutaneous ultrasonic fragmentation procedure performed with the EKOS™ device is highly comparable to the cost of the extirpation procedure performed with the Indigo® System, which is assigned to the higher paying MS–DRGs. The commenter provided the following table to illustrate its findings of the costs for performing a PE procedure among the different devices.

Costs for PE Procedure Among Different Devices			
	EKOS™ Boston Scientific	**FlowTriever®** Inari Medical	**Indigo® System** Penumbra
Device costs	~$6,000	~$9,400	~$6,000

According to the commenter, overall, hospital resource utilization is comparable: the length of stay of percutaneous ultrasonic fragmentation procedures with the EKOS™ device is at least as great as if not longer than comparable extirpation procedures based on the SEATTLE II study and Medicare claims data, and device costs are similar to the Indigo® System.

E. Medicare Claims Data Do Not Reflect EKOS™ Cost

The commenter stated that the EKOS™ device obtained FDA indications for PV procedures in July 2008 and for PE in May 2014. The commenter noted that there has not been ICD–10 procedure coding specific to EKOS™, and the American Hospital Association (AHA) recommended a combination of codes to describe the use of EKOS™ in PE procedures in late 2014:

- 6A750Z7 Ultrasound therapy of vessels, single
- 3E06317 Introduction of other thrombolytic into central artery, percutaneous approach

The commenter conducted its own analysis for the following ICD–10–PCS procedure codes describing the use of ultrasound and the percutaneous introduction of thrombolytics and noted they found 544 claims, with 408 of those assigned to MS–DRG 175 (Pulmonary Embolism with MCC or Acute Cor Pulmonale) and 116 of those assigned to MS–DRG 176 (Pulmonary Embolism without MCC). According to the commenter, while the AHA coding recommendation was helpful, it was unable to provide an accurate assessment of volumes and costs.

Procedure Code	Description
6A750Z7	Ultrasound therapy of other vessels, single
6A750ZZ	Ultrasound therapy, circulatory, single
6A751Z7	Ultrasound therapy of other vessels, multiple
6A751ZZ	Ultrasound therapy, circulatory, multiple
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach

F. Medicare Precedent Exists for Assignment of New Codes to Higher Paying Groups

The commenter stated there is precedent for CMS to use its discretion to assign new codes to higher paying groups, such as the APCs and MS–DRGs. The commenter provided an example of the 2020 Outpatient Prospective Payment System (OPPS) Proposed Rule and noted that CMS proposed assigning two new procedure codes for describing percutaneous creation of AV fistula to a lower level endovascular APC and after reviewing comments, CMS decided to reconsider this recommendation and ultimately assigned the codes to a higher level endovascular APC, as noted in the 2020 OPPS final rule.

Finally, the commenter provided the following table that identifies the procedure codes describing fragmentation of pulmonary and peripheral vascular structures and the proposed O.R., MDC, and MS–DRG assignments for the codes as shown in

Table 6B—New Procedure Codes associated with the proposed rule. The commenter added a column with its requested MS–DRG assignments, as shown in the last column to the right.

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Procedure Code	Description	O.R.	MDC	Proposed MS-DRG	Requested MS-DRG
02FP3Z0	Fragmentation of pulmonary trunk, percutaneous approach, ultrasonic	Y	04	166, 167, 168	163, 164, 165
			05	250, 251	270, 271, 272
				987, 988, 989	987, 988, 989
02FQ3Z0	Fragmentation of right pulmonary artery, percutaneous approach, ultrasonic	Y	04	166, 167, 168	163, 164, 165
			05	250, 251	270, 271, 272
				987, 988, 989	987, 988, 989
02FR3Z0	Fragmentation of left pulmonary artery, percutaneous approach, ultrasonic	Y	04	166, 167, 168	163, 164, 165
			05	250, 251	270, 271, 272
				987, 988, 989	987, 988, 989
02FS3Z0	Fragmentation of right pulmonary vein, percutaneous approach, ultrasonic	Y	04	166, 167, 168	163, 164, 165
			05	250, 251	270, 271, 272
				987, 988, 989	987, 988, 989
02FT3Z0	Fragmentation of left pulmonary vein, percutaneous approach, ultrasonic	Y	04	166, 167, 168	163, 164, 165
			05	250, 251	270, 271, 272
				987, 988, 989	987, 988, 989
03F23Z0	Fragmentation of innominate artery, percutaneous approach, ultrasonic	Y	04	166, 167, 168	163, 164, 165
			05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
03F33Z0	Fragmentation of right subclavian artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
03F43Z0	Fragmentation of left subclavian artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
03F53Z0	Fragmentation of right axillary artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03F63Z0	Fragmentation of left axillary artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03F73Z0	Fragmentation of right brachial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03F83Z0	Fragmentation of left brachial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254

				987, 988, 989	987, 988, 989
03F93Z0	Fragmentation of right ulnar artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03FA3Z0	Fragmentation of left ulnar artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03FB3Z0	Fragmentation of right radial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03FC3Z0	Fragmentation of left radial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
03FY3Z0	Fragmentation of upper artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
04FC3Z0	Fragmentation of right common iliac artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FD3Z0	Fragmentation of left common iliac artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FE3Z0	Fragmentation of right internal iliac artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FF3Z0	Fragmentation of left internal iliac artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FH3Z0	Fragmentation of right external iliac artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FJ3Z0	Fragmentation of left external iliac artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FK3Z0	Fragmentation of right femoral artery, percutaneous approach,	Y	05	252, 253, 254	270, 271, 272

	ultrasonic				
				987, 988, 989	987, 988, 989
04FL3Z0	Fragmentation of left femoral artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FM3Z0	Fragmentation of right popliteal artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FN3Z0	Fragmentation of left popliteal artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FP3Z0	Fragmentation of right anterior tibial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FQ3Z0	Fragmentation of left anterior tibial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FR3Z0	Fragmentation of right posterior tibial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FS3Z0	Fragmentation of left posterior tibial artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FT3Z0	Fragmentation of right peroneal artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FU3Z0	Fragmentation of left peroneal artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
04FY3Z0	Fragmentation of lower artery, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
05F33Z0	Fragmentation of right innominate vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989

05F43Z0	Fragmentation of left innominate vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
05F53Z0	Fragmentation of right subclavian vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
05F63Z0	Fragmentation of left subclavian vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
05F73Z0	Fragmentation of right axillary vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05F83Z0	Fragmentation of left axillary vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05F93Z0	Fragmentation of right brachial vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05FA3Z0	Fragmentation of left brachial vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05FB3Z0	Fragmentation of right basilic vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05FC3Z0	Fragmentation of left basilic vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05FD3Z0	Fragmentation of right cephalic vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05FF3Z0	Fragmentation of left cephalic vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	252, 253, 254
				987, 988, 989	987, 988, 989
05FY3Z0	Fragmentation of upper vein, percutaneous	Y	05	252, 253, 254	252, 253, 254

	approach, ultrasonic				
				987, 988, 989	987, 988, 989
06FC3Z0	Fragmentation of right common iliac vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FD3Z0	Fragmentation of left common iliac vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FF3Z0	Fragmentation of right external iliac vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FG3Z0	Fragmentation of left external iliac vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FH3Z0	Fragmentation of right hypogastric vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FJ3Z0	Fragmentation of left hypogastric vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FM3Z0	Fragmentation of right femoral vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FN3Z0	Fragmentation of left femoral vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FP3Z0	Fragmentation of right saphenous vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FQ3Z0	Fragmentation of left saphenous vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989
06FY3Z0	Fragmentation of lower vein, percutaneous approach, ultrasonic	Y	05	252, 253, 254	270, 271, 272
				987, 988, 989	987, 988, 989

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Another commenter indicated it was made aware of comments being submitted in response to the FY 2021 IPPS/LTCH PPS proposed rule regarding fragmentation codes (04FC3ZZ through 04FY3ZZ). This commenter noted that

in each case, the commenter's request was for CMS to revise the MS–DRG assignment of the fragmentation codes listed in the FY 2021 IPPS/LTCH PPS proposed rule, from MS–DRGs 252, 253 and 254 to MS–DRGs 270, 271 and 272, which include extirpation procedures, by stating that fragmentation procedures are clinically and economically similar to extirpation procedures. The commenter stated it disagreed with the comparison provided in these comments and specifically with the comment that intravascular lithotripsy (IVL) fragmentation is more like extirpation of matter than like other intraluminal balloon-based procedures. This commenter further disagreed that fragmentation and extirpation are of similar complexity or accomplish the same treatment intent in peripheral vascular disease, especially for patients with critical limb ischemia. The commenter requested that CMS maintain its current proposed assignments of the new ICD–10–PCS codes for IVL procedures (04FC3ZZ through 04FY3ZZ) to the MS–DRGs as described in the proposed rule, and defer any changes to MS–DRG assignments until such time that additional long-term clinical and economic data become available to evaluate the new IVL procedures described by these new codes.

Response: We appreciate the commenters' feedback on the proposed MS–DRG assignments for the procedure codes that capture ultrasound accelerated thrombolysis performed with the EkoSonic™ Endovascular System (EKOS™), identified as ultrasonic fragmentation procedures as displayed in Table 6B.—New Procedure Codes, associated with the proposed rule and available via the internet on the CMS web page: (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). We refer the reader to the table above for the list of ICD–10–PCS procedure codes submitted by a commenter that accurately identifies the procedure codes describing fragmentation of pulmonary and peripheral vascular structures with ultrasound and the proposed O.R., MDC, and MS–DRG assignments as shown in Table 6B—New Procedure Codes associated with the proposed rule, that are effective October 1, 2020 for reporting ultrasound assisted thrombolysis.

As noted in prior rulemaking (85 FR 32543), for new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. Consistent with our established process, we examined the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. The predecessor codes for the new procedure codes describing fragmentation of pulmonary and peripheral vascular structures with ultrasound as shown in the September 10, 2019 ICD–10 Coordination and Maintenance Committee meeting materials are 6A750Z7 (Ultrasound therapy of other vessels, single) and 3E06317 (Introduction of other thrombolytic into central artery, percutaneous approach) or 3E05317 (Introduction of other thrombolytic into peripheral artery, percutaneous approach). Because these procedure codes are designated as non-O.R. they do not impact the MS–DRG assignment. Therefore, when any combination of these procedure codes is currently reported, case assignment is dependent upon the principal diagnosis, any secondary diagnoses, and whether or not any other procedures may have been performed and reported on the claim. The MS–DRG assignment for cases with a principal diagnosis of PE is generally medical MS–DRG 175 (Pulmonary Embolism with MCC or Acute Cor Pulmonale) or medical MS–DRG 176 (Pulmonary Embolism without MCC). The MS–DRG assignment for cases with a principal diagnosis of DVT is generally medical MS–DRG 299, 300, or 301 (Peripheral Vascular Disorders with MCC, with CC, and without CC/MCC, respectively). Therefore, cases currently reporting the use of ultrasound accelerated thrombolysis for PE or DVT would generally be assigned to one of those medical MS–DRGs.

The commenters are correct that there are different types of devices available in the treatment of pulmonary embolism (PE) and deep venous thrombosis (DVT). The commenters are also correct that some devices remove matter (clot, thrombus, etc.) while others fragment (break up) matter, with or without the use of thrombolytics. Under the ICD–10–PCS procedure classification system there are two root operations, extirpation and fragmentation, specifically defined as:

Extirpation: Taking or cutting out solid matter from a body part

Fragmentation: Breaking solid matter in a body part into pieces

that are reported to describe the respective procedure that was performed. Because the EKOS™ device fragments matter, procedures performed utilizing this device are identified and described by the root operation Fragmentation, as shown in the titles of the procedure codes listed in the table previously mentioned and discussed above. We do not agree that a change in the proposed MS–DRG assignments for the procedure codes describing ultrasound assisted thrombolysis with the root operation Fragmentation is warranted at this time. We appreciate the information provided by the commenters, however, our clinical advisors do not believe that the treatment difficulty, resource utilization and complexity of service for fragmentation and extirpation procedures are similar in the treatment of PE and DVT. In response to the commenter's statement that both extirpation codes and percutaneous ultrasonic fragmentation codes are reporting services that are intended to reduce clot burden, our clinical advisors agree, however, as shown above, each of these procedures are defined by clinically distinct definitions and objectives, and why there are separate and unique ICD–10–PCS procedure codes within the classification for reporting purposes. Our clinical advisors also do not believe it is appropriate to specifically compare the devices being utilized in the performance of these distinct procedures in consideration of MS–DRG assignment (as the assignment is not related to a new technology add-on payment application), rather, the emphasis is on the fragmentation and extirpation procedures performed and evaluating the treatment difficulty, resource utilization and complexity of service.

With respect to the commenter's statement that PE percutaneous ultrasonic fragmentation procedures are not clinically similar to other procedures assigned to MS–DRGs 166, 167, and 168, and PV percutaneous ultrasonic fragmentation procedures are not clinically similar to other procedures assigned to MS–DRGs 252, 253, and 254, we note that, as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The

other classes would include diagnoses or procedures which were infrequently encountered or not well defined clinically. For example, the ''other'' medical class for the Respiratory System MDC would contain the diagnoses ''other somatoform disorders'' and ''congenital malformation of the respiratory system,'' while the ''other'' surgical class for the female reproductive MDC would contain the surgical procedures ''excision of liver'' (liver biopsy in ICD–9–CM) and ''inspection of peritoneal cavity'' (exploratory laparotomy in ICD–9–CM). The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. There are, however, also patients who receive surgical procedures which are completely unrelated to the MDC to which the patient was assigned. An example of such a patient would be a patient with a principal diagnosis of pneumonia whose only surgical procedure is a destruction of prostate (transurethral prostatectomy in ICD–9–CM). Such patients are assigned to a surgical class referred to as ''unrelated operating room procedures.'' These patients are ultimately never assigned to a well-defined DRG.'' We further note that MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) are examples of the ''other'' surgical class, therefore it is expected that there will be procedures not precisely clinically aligned within the definition (logic) of these MS–DRGs.

We appreciate the commenter's feedback and information pertaining to the pivotal trials that have been conducted, however, as stated previously, fragmentation and extirpation procedures are clinically distinct and separate procedures, uniquely defined within the classification, and our clinical advisors do not believe it is appropriate to specifically compare the devices being utilized in the performance of these distinct procedures with respect to resource utilization and in consideration of MS–DRG assignment. As discussed earlier in this section, we followed our established process for determining the most appropriate MS–DRG assignment for new procedure codes.

We acknowledge the claims analysis conducted by the commenter and because the current procedure codes do not uniquely identify and describe ultrasound accelerated thrombolysis we concur it is difficult to accurately assess the data.

The ICD–10–CM diagnosis codes that identify pulmonary embolism and acute cor pulmonale that are included in the logic for MS–DRGs 175 and 176 are:

ICD-10-CM Code	Code Description
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.92	Saddle embolus of pulmonary artery without acute cor pulmonale
I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale
I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.82	Chronic pulmonary embolism
T79.0XXA	Air embolism (traumatic), initial encounter
T79.1XXA	Fat embolism (traumatic), initial encounter
T80.0XXA	Air embolism following infusion, transfusion and therapeutic injection, initial encounter

We analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting fragmentation procedures in MS–DRGs 175 and 176 with a principal diagnosis of PE and procedure codes 6A750Z7 with 3E06317 to identify the use of fragmentation via ultrasound and thrombolytics. Our findings are shown in the following table.

Pulmonary Embolism with Ultrasound and Thrombolytics				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
175	All Cases	27,843	5.0	$10,515
	Cases with principal diagnosis of PE with ultrasound and thrombolytics	235	5.0	$21,191
176	All Cases	26,568	3.1	$6,268
	Cases with principal diagnosis PE with ultrasound and thrombolytics	62	3.8	$19,035

The data demonstrates that the 297 cases reporting a principal diagnosis of PE with the use of ultrasound and thrombolytics in MS–DRGs 175 and 176 (235+62=297) have higher average costs compared to all the cases in MS–DRGs 175 and 176 ($21,191 versus $10,515 and $19,035 versus $6,268, respectively) and a comparable average length of stay (5.0 days versus 5.0 days and 3.8 days versus 3.1 days, respectively).

The ICD–10–CM diagnosis codes that identify DVT that are included in the logic for MS–DRGs 299, 300 and 301 are:

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ICD-10-CM Code	Code Description
I82.401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity
I82.402	Acute embolism and thrombosis of unspecified deep veins of left lower extremity
I82.403	Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.411	Acute embolism and thrombosis of right femoral vein
I82.412	Acute embolism and thrombosis of left femoral vein
I82.413	Acute embolism and thrombosis of femoral vein, bilateral
I82.419	Acute embolism and thrombosis of unspecified femoral vein
I82.421	Acute embolism and thrombosis of right iliac vein
I82.422	Acute embolism and thrombosis of left iliac vein
I82.423	Acute embolism and thrombosis of iliac vein, bilateral
I82.429	Acute embolism and thrombosis of unspecified iliac vein
I82.431	Acute embolism and thrombosis of right popliteal vein
I82.432	Acute embolism and thrombosis of left popliteal vein
I82.433	Acute embolism and thrombosis of popliteal vein, bilateral
I82.439	Acute embolism and thrombosis of unspecified popliteal vein
I82.441	Acute embolism and thrombosis of right tibial vein
I82.442	Acute embolism and thrombosis of left tibial vein
I82.443	Acute embolism and thrombosis of tibial vein, bilateral
I82.449	Acute embolism and thrombosis of unspecified tibial vein
I82.451	Acute embolism and thrombosis of right peroneal vein
I82.452	Acute embolism and thrombosis of left peroneal vein
I82.453	Acute embolism and thrombosis of peroneal vein, bilateral
I82.459	Acute embolism and thrombosis of unspecified peroneal vein
I82.461	Acute embolism and thrombosis of right calf muscular vein
I82.462	Acute embolism and thrombosis of left calf muscular vein
I82.463	Acute embolism and thrombosis of calf muscular vein, bilateral

I82.469	Acute embolism and thrombosis of unspecified calf muscular vein
I82.491	Acute embolism and thrombosis of other specified deep vein of right lower extremity
I82.492	Acute embolism and thrombosis of other specified deep vein of left lower extremity
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.4Y1	Acute embolism and thrombosis of unspecified deep veins of right proximal lower extremity
I82.4Y2	Acute embolism and thrombosis of unspecified deep veins of left proximal lower extremity
I82.4Y3	Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral
I82.4Y9	Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
I82.4Z1	Acute embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.4Z2	Acute embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.4Z3	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
I82.501	Chronic embolism and thrombosis of unspecified deep veins of right lower extremity
I82.502	Chronic embolism and thrombosis of unspecified deep veins of left lower extremity
I82.503	Chronic embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I82.509	Chronic embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.511	Chronic embolism and thrombosis of right femoral vein
I82.512	Chronic embolism and thrombosis of left femoral vein
I82.513	Chronic embolism and thrombosis of femoral vein, bilateral
I82.519	Chronic embolism and thrombosis of unspecified femoral vein
I82.521	Chronic embolism and thrombosis of right iliac vein
I82.522	Chronic embolism and thrombosis of left iliac vein
I82.523	Chronic embolism and thrombosis of iliac vein, bilateral
I82.529	Chronic embolism and thrombosis of unspecified iliac vein
I82.531	Chronic embolism and thrombosis of right popliteal vein
I82.532	Chronic embolism and thrombosis of left popliteal vein
I82.533	Chronic embolism and thrombosis of popliteal vein, bilateral

I82.539	Chronic embolism and thrombosis of unspecified popliteal vein
I82.541	Chronic embolism and thrombosis of right tibial vein
I82.542	Chronic embolism and thrombosis of left tibial vein
I82.543	Chronic embolism and thrombosis of tibial vein, bilateral
I82.549	Chronic embolism and thrombosis of unspecified tibial vein
I82.551	Chronic embolism and thrombosis of right peroneal vein
I82.552	Chronic embolism and thrombosis of left peroneal vein
I82.553	Chronic embolism and thrombosis of peroneal vein, bilateral
I82.559	Chronic embolism and thrombosis of unspecified peroneal vein
I82.561	Chronic embolism and thrombosis of right calf muscular vein
I82.562	Chronic embolism and thrombosis of left calf muscular vein
I82.563	Chronic embolism and thrombosis of calf muscular vein, bilateral
I82.569	Chronic embolism and thrombosis of unspecified calf muscular vein
I82.591	Chronic embolism and thrombosis of other specified deep vein of right lower extremity
I82.592	Chronic embolism and thrombosis of other specified deep vein of left lower extremity
I82.593	Chronic embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.599	Chronic embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.5Y1	Chronic embolism and thrombosis of unspecified deep veins of right proximal lower extremity
I82.5Y2	Chronic embolism and thrombosis of unspecified deep veins of left proximal lower extremity
I82.5Y3	Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral
I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
I82.5Z1	Chronic embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.5Z2	Chronic embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.5Z3	Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity

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We also examined claims for cases reporting fragmentation procedures in MS–DRGs 299, 300 and 301 with a principal diagnosis of DVT and procedure codes 6A750Z7 with 3E06317 to identify the use of fragmentation via ultrasound and thrombolytics. Our findings are shown in the following table.

Deep Venous Thrombosis with Ultrasound and Thrombolytics				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
299	All Cases	17,393	5.2	$10,611
	Principal diagnosis of DVT with ultrasound and thrombolytics	3	3.3	$15,942
300	All Cases	25,937	3.9	$7,378
	Principal diagnosis of DVT with ultrasound and thrombolytics	1	4.0	$12,930
301	All Cases	6,951	2.7	5,350

The data demonstrates that the 4 cases reporting a principal diagnosis of DVT with the use of ultrasound and thrombolytics in MS–DRGs 299 and 300 (3+1=4) have higher average costs compared to all the cases in MS–DRGs 299 and 300 ($15,942 versus $10,611 and $12,930 versus $7,378, respectively) and a comparable average length of stay (3.3 days versus 5.2 days and 4.0 days versus 3.9 days, respectively). We note that there were no cases found reporting a principal diagnosis of DVT with the use of ultrasound and thrombolytics in MS–DRG 301.

We then analyzed claims data from the September 2019 update of the FY 2019 MedPAR data for MS–DRGs 163, 164, and 165 and MS–DRGs 270, 271, and 272. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
163 – All cases	10,203	11.6	$34,718
164 – All cases	14,824	5.4	$19,120
165 – All cases	7,677	3.1	$13,938
270 – All cases	17,816	9.4	$37,100
271 – All cases	13,733	5.8	$28,219
272 – All cases	4,987	2.6	$19,789

Overall, the data demonstrates that cases reporting a principal diagnosis of PE with ultrasound and thrombolytic (fragmentation) in MS–DRG 175 have average costs and an average length of stay that are less than the average costs and average length of stay of all the cases in MS–DRG 163 ($21,191 versus $34,718) and (5.0 days versus 11.6 days). The data also demonstrates that cases reporting a principal diagnosis of PE with ultrasound and thrombolytic (fragmentation) in MS–DRG 176 have average costs and an average length of stay that are less than the average costs and average length of stay of all the cases in MS–DRG 164 ($19,035 versus $19,120) and (3.8 days versus 5.4 days). We note that because MS–DRG 175 is the ''with MCC'' MS–DRG and MS–DRG 176 is the ''without MCC'' (CC+NonCC) MS–DRG that it's possible a subset of the 62 cases found reporting a principal diagnosis of PE with ultrasound and thrombolytic in MS–DRG 176 did not report a CC and those cases would then be compared to MS–DRG 165, however, we were unable to analyze the detailed data for the 62 cases.

The data demonstrates that cases reporting a principal diagnosis of DVT with ultrasound and thrombolytic (fragmentation) in MS–DRG 299 have average costs and an average length of stay that are less than the average costs and average length of stay of all the cases in MS–DRG 270 ($15,942 versus $37,100) and (3.3 days versus 9.4 days). The data also demonstrates that cases reporting a principal diagnosis of DVT with ultrasound and thrombolytic (fragmentation) in MS–DRG 300 have average costs and an average length of stay that are less than the average costs and average length of stay of all the cases in MS–DRG 271 ($12,930 versus $28,219) and (4.0 days versus 5.8 days). For these reasons, based on the claims analysis, our clinical advisors do not support assignment of the new procedure codes describing fragmentation via ultrasound accelerated thrombolysis for the treatment of PE to MS–DRGs 163, 164, and 165 or to MS–DRGs 270, 271, and 272 for the treatment of DVT.

We then analyzed claims data from the September 2019 update of the FY 2019 MedPAR data for MS–DRGs 166, 167, and 168 and MS–DRGs 252, 253, and 254. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
166 – All cases	11,380	10.3	$26,702
167 – All cases	6,575	4.9	$13,556
168 – All cases	2,189	2.6	$10,149
252 – All cases	33,444	7.5	$24,369
253 – All cases	23,905	5.4	$19,316
254 – All cases	10,236	2.6	$13,302

Overall, the data demonstrates that cases reporting a principal diagnosis of PE with ultrasound and thrombolytic (fragmentation) in MS–DRG 175 have average costs and an average length of stay that are more consistent with the average costs and average length of stay of all the cases in MS–DRG 166 ($21,191 versus $26,702) and (5.0 days versus 10.3 days). The data also demonstrates that cases reporting a principal diagnosis of PE with ultrasound and thrombolytic (fragmentation) in MS–DRG 176 have average costs and an average length of stay that are more consistent with the average costs and average length of stay of all the cases in MS–DRG 167 ($19,035 versus $13,566) and (3.8 days versus 4.9 days). We note that it's possible that a subset of the 62 cases found reporting a principal diagnosis of PE with ultrasound and thrombolytic in MS–DRG 176 did not report a CC and those cases would then be compared to MS–DRG 168, however, we were unable to analyze the detailed data for the 62 cases.

The data also demonstrates that cases reporting a principal diagnosis of DVT with ultrasound and thrombolytic (fragmentation) in MS–DRG 299 have average costs and an average length of stay that are more consistent with the average costs and average length of stay of all the cases in MS–DRG 252 ($15,942 versus $24,369) and (3.3 days versus 7.5 days). The data also demonstrates that cases reporting a principal diagnosis of DVT with ultrasound and thrombolytic (fragmentation) in MS–DRG 300 have average costs and an average length of stay that are more consistent with the average costs and average length of stay of all the cases in MS–DRG 253 ($12,930 versus $19,316) and (4.0 days versus 5.4 days). As previously noted, there were no cases found reporting a principal diagnosis of DVT with ultrasound and thrombolytic (fragmentation) in MS–DRG 301. For these reasons, our clinical advisors stated the claims analysis supports assignment of the new procedure codes describing fragmentation via ultrasound accelerated thrombolysis for the treatment of PE to MS–DRGs 166, 167, and 168 and to MS–DRGs 252, 253, and 254 for the treatment of DVT.

With respect to the commenter who stated it disagreed with the comparison provided in the other comments, specifically for IVL fragmentation, we appreciate the commenter's feedback, however, we believe that the commenter expressed concerns regarding a different subset of procedure codes that are also reported with the root operation fragmentation. The procedure codes describing fragmentation that are reported to identify an IVL procedure was performed do not include the term ''ultrasonic'' that is reported with the 7th digit character qualifier value of ''0'' for the ultrasound accelerated thrombolysis procedures. Alternatively, the procedure codes describing fragmentation that are reported to identify an IVL procedure was performed are reported with the 7th digit character qualifier value of ''Z''.

After consideration of the public comments we received, and for reasons previously discussed, we are finalizing our proposal to assign the ultrasound accelerated thrombolysis procedures described by the root operation fragmentation and performed for the treatment of PE to MS–DRGs 166, 167, and 168 and for the treatment of DVT to MS–DRGs 252, 253, and 254 as proposed in Table 6B—New Procedure Codes associated with the proposed rule, and shown in Table 6B—New Procedure Codes associated with this final rule.

We note that, as stated in prior rule making (84 FR 42148), our clinical advisors recognize that MS–DRGs 163, 164, 165, 166, 167, and 168 may warrant further review and therefore, we plan to begin conducting this detailed review beginning with our FY 2022 MS–DRG classification analysis of claims data and determine what modifications may need to be considered for future rulemaking.

Comment: A commenter expressed concern that ICD–10–PCS procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) did not have an O.R. procedure status proposed for FY 2021 as displayed in Table 6—New Procedure Codes associated with the proposed rule. According to the commenter, this new procedure code should have O.R. status because it involves traversing the skull in order to place a substance within the cranial cavity or brain. The commenter stated that the skull must be opened by drilling/cutting a burr hole and that although percutaneous (burr hole) procedures are performed through smaller openings in the skull than larger open burr hole procedures, they nonetheless require drilling through the skull under sterile technique with anesthesia for pain control. The commenter also stated that specialized equipment for a stereotactic approach, image-guidance and/or endoscope is required. Lastly, the commenter reported that other percutaneous procedures (including drainages) of the cranial cavities and brain have been discussed with CMS and appropriately re-classified to OR procedure status.

Response: We appreciate the commenter's feedback. Consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs, and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW0Q316 is procedure code 3E0Q3GC (Introduction of other therapeutic substance into cranial cavity and brain, percutaneous approach) which is designated as a non-O.R. procedure. In the absence of claims data, our clinical advisors also considered the indication for the specific procedure being described by the new procedure code, the treatment difficulty, and the resources utilized. Upon review, our clinical advisors do not believe that a change in the O.R. status for this procedure is warranted at this time.

After consideration of the comment we received, we are finalizing our proposal to designate procedure code XW0Q316 as non-O.R. for FY 2021. As claims data becomes available for this procedure we can reevaluate for future rule making.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this final rule:

- Table 6A—New Diagnosis Codes–FY 2021;
- Table 6B—New Procedure Codes–FY 2021;
- Table 6C—Invalid Diagnosis Codes–FY 2021;
- Table 6E—Revised Diagnosis Code Titles–FY 2021;
- Table 6G.1—Secondary Diagnosis Order Additions to the CC Exclusions List–FY 2021;
- Table 6G.2—Principal Diagnosis Order Additions to the CC Exclusions List–FY 2021;
- Table 6H.1—Secondary Diagnosis Order Deletions to the CC Exclusions List–FY 2021;
- Table 6H.2—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021;
- Table 6I—Complete MCC List–FY 2021;
- Table 6I.1—Additions to the MCC List–FY 2021;
- Table 6I.2–Deletions to the MCC List–FY 2021;
- Table 6J—Complete CC List –FY 2021;
- Table 6J.1—Additions to the CC List–FY 2021;
- Table 6J.2—Deletions to the CC List –FY 2021; and
- Table 6K—Complete List of CC Exclusions –FY 2021.14. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42156), we made available the FY 2020 ICD–10 MCE Version 37 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 37 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software.*

In the FY 2021 IPPS/LTCH PPS proposed rule, we addressed the MCE requests we received by the November 1, 2019 deadline. We also discussed the proposals we were making based on internal review and analysis. In this FY 2021 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to the MCE requests and proposals presented based on internal reviews and analyses in the proposed rule, our responses to those comments, and our finalized policies.

In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we have only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we are making available the FY 2021 ICD–10 MCE Version 38 Manual file, along with the link to the mainframe and computer software for the MCE Version 38 (and ICD–10 MS–DRGs), on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

a. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity diagnoses category for the Age conflict edit considers the age range of 9 to 64 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the Maternity diagnoses category code list under the Age conflict edit.

ICD-10-CM Code	Code Description
O34.218	Maternal care for other type scar from previous cesarean delivery
O34.22	Maternal care for cesarean scar defect (isthmocele)
O99.891	Other specified diseases and conditions complicating pregnancy
O99.892	Other specified diseases and conditions complicating childbirth
O99.893	Other specified diseases and conditions complicating puerperium

In addition, as discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table is ICD–10–CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) which is currently listed on the Maternity diagnoses category code list under the Age Conflict edit. We proposed to remove this code from the Maternity diagnoses category code list.

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the previous table to the Maternity diagnoses category code list under the Age conflict edit. Commenters also agreed to remove ICD–10–CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) from the Maternity diagnoses category edit code list under the Age Conflict edit since it is no longer a valid code effective October 1, 2020.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Maternity diagnoses category edit code list and our proposal to remove ICD–10–CM diagnosis code O99.89 from the Maternity diagnoses category edit code list under the ICD–10 MCE Version 38, effective October 1, 2020.

(2) Adult Diagnoses

Under the ICD–10 MCE, the Adult diagnoses category for the Age conflict edit considers the age range of 15 to 124 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–CM diagnosis codes to the Adult diagnoses category code list under the Age conflict edit.

ICD-10-CM Code	Code Description
M80.0AXA	Age-related osteoporosis with current pathological fracture, other site, initial encounter for fracture
M80.0AXD	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.0AXG	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.0AXK	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion
M80.0AXP	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.0AXS	Age-related osteoporosis with current pathological fracture, other site, sequela

Comment: Commenters supported the proposal to add the diagnosis codes listed in the previous table to the Adult diagnoses category code list under the Age conflict edit.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Adult diagnoses category edit code list under the ICD–10 MCE Version 38, effective October 1, 2020.

b. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Females Only Edit

As discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective

with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the edit code list for the Diagnoses for Females Only edit.

ICD-10-CM Code	Code Description
O34.218	Maternal care for other type scar from previous cesarean delivery
O34.22	Maternal care for cesarean scar defect (isthmocele)
O99.891	Other specified diseases and conditions complicating pregnancy
O99.892	Other specified diseases and conditions complicating childbirth
O99.893	Other specified diseases and conditions complicating puerperium

In addition, as discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table are ICD–10–CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) and ICD–10–CM diagnosis code Q51.20 (Other doubling of uterus, unspecified) which are currently listed on the Diagnoses for Females Only edit code list. We proposed to delete these codes from the Diagnoses for Females Only edit code list.

Comment: Commenters supported the proposal to add the ICD–10–CM diagnosis codes listed in the previous table to the Diagnoses for Females Only edit code list and to remove ICD–10–CM diagnosis codes O99.89 and Q51.20 from the list of diagnosis codes for the Diagnoses for Females Only edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add the diagnosis codes displayed in the previous table to the Diagnoses for Females Only edit code list and our proposal to remove ICD–10–CM diagnosis code O99.89 and Q51.20 from the Diagnoses for Females Only edit code list under the ICD–10 MCE Version 38, effective October 1, 2020.

(2) Procedures for Females Only Edit

As discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6B—New Procedure Codes, lists the new procedure codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–PCS procedure codes listed in this section of this rule to the edit code list for the Procedures for Females Only edit.

ICD-10-PCS Code	Code Description
DU10B6Z	Low dose rate (LDR) brachytherapy of ovary using Cesium 131 (Cs-131)
DU11B6Z	Low dose rate (LDR) brachytherapy of cervix using Cesium 131 (Cs-131)
DU12B6Z	Low dose rate (LDR) brachytherapy of uterus using Cesium 131 (Cs-131)

Comments: Commenters supported our proposal to add the ICD–10–PCS procedure codes listed in the previous table to the edit code list for the Procedures for Females Only edit.

Response: We thank the commenters for their support.

After consideration of the public comments that we received, we are finalizing our proposal to add the ICD–10–PCS procedure codes listed in the previous table to the edit code list for the Procedures for Females Only edit under the ICD–10 MCE Version 38, effective October 1, 2020.

(3) Procedures for Males Only

As discussed in section II.D.13. of the preamble of the proposed rule and in section II.E.13. of this final rule, Table 6B—New Procedure Codes, lists the new procedure codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–PCS procedure codes listed in this section of this rule to the edit code list for the Procedures for Males Only edit.

ICD-10-PCS Code	Code Description
DV10B6Z	Low dose rate (LDR) brachytherapy of prostate using Cesium 131 (Cs-131)
DV11B6Z	Low dose rate (LDR) brachytherapy of testis using Cesium 131 (Cs-131)

Comments: Commenters agreed with our proposal to add the ICD–10–PCS procedure codes listed in the previous table to the edit code list for the Procedures for Males Only edit.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add the ICD–10–PCS procedure codes listed in the previous table to the edit code list for the Procedures for Males Only edit under the ICD–10 MCE Version 38, effective October 1, 2020.

c. Manifestation Code as Principal Diagnosis Edit

In the ICD–10–CM classification system, manifestation codes describe the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6A—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the edit code list for the Manifestation Codes Not Allowed as Principal Diagnosis edit code list because these codes are describing the manifestation of an underlying disease and not the disease itself.

ICD-10-CM Code	Code Description
D72.18	Eosinophilia in diseases classified elsewhere
D84.81	Immunodeficiency due to conditions classified elsewhere
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere

Comment: We received comments in support of our proposal to add the codes listed in the previous table to the Manifestation Codes Not Allowed as Principal Diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments that we received, we are finalizing our proposal to add the ICD–10–CM diagnosis codes listed in the previous table to the edit code list for the Manifestation Codes Not Allowed as Principal Diagnosis edit under the ICD–10 MCE Version 38, effective October 1, 2020.

In addition, as discussed in section II.D.13. of the preamble of the proposed rule and in section II.E.13. of this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table is ICD–10–CM diagnosis code J84.17 (Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere) which is currently listed on the Manifestation Codes Not Allowed as Principal Diagnosis edit code list. We proposed to delete this code from the Manifestation Codes Not Allowed as Principal Diagnosis edit code list.

Comment: Commenters agreed with the proposal to delete ICD–10–CM diagnosis code J84.17 (Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere) from the Manifestation Codes Not Allowed as Principal Diagnosis edit code list.

Response: We appreciate the commenters' support of our proposal.

After consideration of the public comments that we received, we are finalizing our proposal to delete ICD–10–CM diagnosis code J84.17 from the Manifestation Codes Not Allowed as Principal Diagnosis edit code list under the ICD–10 MCE Version 38, effective October 1, 2020.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in Section II.D.13. of the preamble of the proposed rule and section II.E.13. of this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We proposed to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Code Description
D89.831	Cytokine release syndrome, grade 1
D89.832	Cytokine release syndrome, grade 2
D89.833	Cytokine release syndrome, grade 3
D89.834	Cytokine release syndrome, grade 4
D89.835	Cytokine release syndrome, grade 5
D89.839	Cytokine release syndrome, grade unspecified
K74.00	Hepatic fibrosis, unspecified
K74.01	Hepatic fibrosis, early fibrosis
K74.02	Hepatic fibrosis, advanced fibrosis
T40.415A	Adverse effect of fentanyl or fentanyl analogs, initial encounter
T40.415D	Adverse effect of fentanyl or fentanyl analogs, subsequent encounter
T40.415S	Adverse effect of fentanyl or fentanyl analogs, sequela
T40.416A	Underdosing of fentanyl or fentanyl analogs, initial encounter
T40.416D	Underdosing of fentanyl or fentanyl analogs, subsequent encounter
T40.416S	Underdosing of fentanyl or fentanyl analogs, sequela
T40.425A	Adverse effect of tramadol, initial encounter
T40.425D	Adverse effect of tramadol, subsequent encounter
T40.425S	Adverse effect of tramadol, sequela
T40.426A	Underdosing of tramadol, initial encounter
T40.426D	Underdosing of tramadol, subsequent encounter
T40.426S	Underdosing of tramadol, sequela
T40.495A	Adverse effect of other synthetic narcotics, initial encounter
T40.495D	Adverse effect of other synthetic narcotics, subsequent encounter
T40.495S	Adverse effect of other synthetic narcotics, sequela
T40.496A	Underdosing of other synthetic narcotics, initial encounter
T40.496D	Underdosing of other synthetic narcotics, subsequent encounter
T40.496S	Underdosing of other synthetic narcotics, sequela
Z03.821	Encounter for observation for suspected ingested foreign body ruled out
Z03.822	Encounter for observation for suspected aspirated (inhaled) foreign body ruled out
Z03.823	Encounter for observation for suspected inserted (injected) foreign body ruled out

Comment: Commenters supported our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list. However, one commenter disagreed with adding the diagnosis codes describing Cytokine release syndrome (CRS) (D89.831 through D89.839) to the Unacceptable Principal Diagnosis edit code list. The commenter noted that at the ICD–10 Coordination and Maintenance Committee meeting held on September 11–12, 2019, CRS was described as a condition that may occur after treatment with some types of immunotherapy, such as Chimeric Antigen Receptor (CAR) T-cell therapy, and is the most common reaction after CAR T-cell therapy. The commenter stated that if CRS is the reason for the admission and is an adverse effect of the therapy/drug, the diagnosis code for the CRS must be sequenced as the principal diagnosis per coding guidelines, therefore, the CRS diagnosis codes should not be included on the Unacceptable Principal Diagnosis edit code list. This commenter also disagreed with adding diagnosis codes K74.00 (Hepatic fibrosis, unspecified), K74.01 (Hepatic fibrosis, early fibrosis), and K74.02 (Hepatic fibrosis, advanced fibrosis) to the Unacceptable Principal Diagnosis edit code list. The commenter noted that hepatic fibrosis may be determined to be the underlying cause of symptoms such as weakness, nausea, jaundice, or appetite loss in a patient. The commenter also stated that the current diagnosis code, K74.0 (Hepatic fibrosis) is not on the Unacceptable Principal Diagnosis edit code list, therefore, diagnosis codes K74.00, K74.01 and K74.02 should not be included on the Unacceptable Principal Diagnosis edit code list. This same commenter also disagreed with adding diagnosis codes Z03.821 (Encounter for observation for suspected ingested foreign body ruled out), Z03.822 (Encounter for observation for suspected aspirated (inhaled) foreign body ruled out), and Z03.823 (Encounter for observation for suspected inserted (injected) foreign body ruled out) to the Unacceptable Principal Diagnosis edit code list. The commenter stated that

current codes in subcategory Z03.8 are only reportable as principal diagnosis/first listed except when there are multiple encounters on the same day and the medical records for the encounters are combined and therefore, diagnosis codes Z03.821, Z03.822, and Z03.823 should not be included on the Unacceptable Principal Diagnosis edit code list.

Response: We appreciate the commenters' feedback on our proposal. In response to the commenter who disagreed with our proposal to add the diagnosis codes describing Cytokine release syndrome (CRS) (D89.831 through D89.839) to the Unacceptable Principal Diagnosis edit code list, we note that we consulted with the staff at the Centers for Disease Control and Prevention's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes. The NCHS' staff confirmed that they do not consider CAR T-cell therapy to be a drug since it is a gene therapy. They noted that the ICD–10–CM Tabular instruction at subcategory D89.83-(Cytokine release syndrome) has a ''Code first'' that reads:

''Code first underlying cause, such as:
complications following infusion, transfusion and therapeutic injection (T80.89-) complications of transplanted organs and tissue (T86.-)''

They also stated that the intent is for the CRS codes to not be reported as a principal diagnosis. Diagnosis codes K74.00 (Hepatic fibrosis, unspecified), K74.01 (Hepatic fibrosis, early fibrosis), and K74.02 (Hepatic fibrosis, advanced fibrosis) also have a ''Code first'' note at the new subcategory K74.0 (Hepatic fibrosis), effective October 1, 2020. The commenter is correct that currently, diagnosis code K74.0 is not on the Unacceptable Principal Diagnosis Code list and we note that there is not a ''Code first'' note currently at that diagnosis code. We point out that diagnosis code K74.0 has been expanded effective October 1 and is therefore classified as a subcategory. The ICD–10–CM Tabular instruction at new subcategory K74.0 has a ''Code first'' note that reads:

''Code first underlying liver disease, such as:
nonalcoholic steatohepatitis (NASH) (K75.81)''

The ''Code first'' note at this subcategory applies to all three new diagnosis codes, K74.00, K74.01, and K74.02.

In response to the commenter's disagreement with adding diagnosis codes Z03.821 (Encounter for observation for suspected ingested foreign body ruled out), Z03.822 (Encounter for observation for suspected aspirated (inhaled) foreign body ruled out), and Z03.823 (Encounter for observation for suspected inserted (injected) foreign body ruled out) to the Unacceptable Principal Diagnosis edit code list, we note that these diagnosis codes were created in response to a request from the American Academy of Pediatrics, which indicated that since a child is often not able to communicate what occurred, there needs to be a way to identify and track these kinds of encounters, therefore, we would not expect these codes to be reported in our Medicare claims data for an inpatient stay.

After consideration of the public comments that we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 38, effective October 1, 2020.

In addition, as discussed in section II.D.13. of the preamble of the proposed rule and in section II.E.13. of this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the Unacceptable Principal Diagnosis edit code list. We proposed to delete these codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Code Description
T40.4X5A	Adverse effect of other synthetic narcotics, initial encounter
T40.4X5D	Adverse effect of other synthetic narcotics, subsequent encounter
T40.4X5S	Adverse effect of other synthetic narcotics, sequela
T40.4X6A	Underdosing of other synthetic narcotics, initial encounter
T40.4X6D	Underdosing of other synthetic narcotics, subsequent encounter
T40.4X6S	Underdosing of other synthetic narcotics, sequela

Comment: Commenters agreed with our proposal to remove the codes listed in the previous table from the Unacceptable Principal Diagnosis edit code list since they are no longer valid effective October 1, 2020.

Response: We thank the commenters for their support.

After consideration of the public comments that we received, we are finalizing our proposal to remove the diagnosis codes, as previously listed, from the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 38, effective October 1, 2020.

e. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054) we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment and analysis aspects. Subsequently, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235) we stated that we engaged a contractor to assist in the review of the limited coverage and non-covered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what is already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE. The contractor is continuing to conduct this review.

We have also noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY

2019 IPPS/LTCH PPS final rule (83 FR 41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2020.

15. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this final rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable. We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we proposed to make in the FY 2021 IPPS/LTCH PPS proposed rule, as discussed in section II.E.2.b. of the preamble of this final rule, we proposed to revise the surgical hierarchy for the Pre-MDC MS–DRGs as follows: In the Pre-MDC MS–DRGs we proposed to sequence proposed new Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) above Pre-MDC MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively). We also note that, as discussed in section II.D.2.b. of the preamble of the proposed rule and in section II.E.2.b. of this final rule, we proposed to revise the title for Pre-MDC MS–DRG 016 to ''Autologous Bone Marrow Transplant with CC/MCC''. In addition, based on the changes that we proposed to make as discussed in section II.D.8.a. of the preamble of the proposed rule and in section II.E.8.a. of this final rule, we also proposed to sequence proposed new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis) above Pre-MDC MS–DRG 008 (Simultaneous Pancreas/Kidney Transplant) and below Pre-MDC MS–DRG 007 (Lung Transplant).

As discussed in section II.D.4. of the preamble of the proposed rule and section II.E.4. of this final rule, we proposed to delete MS–DRGs 129 (Major Head and Neck Procedures with CC/MCC or Major Device) and MS–DRG 130 (Major Head and Neck Procedures without CC/MCC), MS–DRGs 131 and 132 (Cranial and Facial Procedures with CC/MCC and without CC/MCC, respectively), and MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively). Based on the changes we proposed to make for those MS–DRGs in MDC 03, we proposed to revise the surgical hierarchy for MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat) as follows: In MDC 03, we proposed to sequence proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) above new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We also proposed to sequence proposed new MS–DRGs 143, 144, and 145 above MS–DRGs 135 and 136 (Sinus and Mastoid Procedures with CC/MCC and without CC/MCC, respectively). We also note that, based on the changes that we proposed to make, as discussed in section II.D.7.b. of the preamble of the proposed rule and section II.E.7.b. of this final rule, we proposed to revise the surgical hierarchy for MDC 08 (Diseases and

Disorders of the Musculoskeletal System and Connective Tissue) as follows: In MDC 08, we proposed to sequence proposed new MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively) above MS–DRGs 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement) and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC). We further note that, based on the changes we proposed to make, as discussed in section II.D.8.a. of the preamble of the proposed rule and section II.E.8.a. of this final rule, we proposed to revise the surgical hierarchy for MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) as follows: In MDC 11, we proposed to sequence proposed new MS–DRGs 650 and 651 (Kidney Transplant with Hemodialysis with and without MCC, respectively) above MS–DRG 652 (Kidney Transplant).

Our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 38 is illustrated in the following tables.

Surgical Hierarchy: Pre-MDC MS-DRGs	
Proposed New MS-DRG 018	Chimeric Antigen Receptor (CAR) T-cell Immunotherapy
MS-DRGs 001-002	Heart Transplant or Implant of Heart Assist System
MS-DRGs 003-004	ECMO or Tracheostomy with MV >96 Hours or PDX Except Face, Mouth and Neck
MS-DRGs 005-006	Liver or Intestinal Transplant
MS-DRG 014	Allogeneic Bone Marrow Transplant
MS-DRG 007	Lung Transplant
Proposed New MS-DRG 019	Simultaneous Pancreas/Kidney Transplant with Hemodialysis
MS-DRG 008	Simultaneous Pancreas/Kidney Transplant
MS-DRGs 016-017	Autologous Bone Marrow Transplant
MS-DRG 010	Pancreas
MS-DRG 011-013	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy

Surgical Hierarchy: MDC 03	
Proposed New MS-DRGs 140-142	Major Head and Neck Procedures
Proposed New MS-DRGs 143-145	Other Ear, Nose, Mouth and Throat O.R. Procedures
MS-DRGs 135-136	Sinus and Mastoid Procedures

Surgical Hierarchy: MDC 08	
MS-DRGs 453-455	Combined Anterior/Posterior Spinal Fusion
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature / Malignancy / Infection or Extensive Fusions
MS-DRGs 459-460	Spinal Fusion Except Cervical
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
MS-DRGs 463-465	Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders
MS-DRGs 466-468	Revision of Hip or Knee Replacement
Proposed New MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity

Surgical Hierarchy: MDC 11	
Proposed New MS-DRGs 650-651	Kidney Transplant with Hemodialysis
MS-DRG 652	Kidney Transplant

Comment: Commenters supported our proposal to sequence proposed new Pre-MDC MS–DRG 018 above Pre-MDC MS–DRGs 001 and 002. Commenters also supported our proposal to sequence proposed new Pre-MDC MS–DRG 019 above Pre-MDC MS–DRG 008 and below Pre-MDC MS–DRG 007.

Response: We appreciate the commenters' support. As discussed in section II.E.2.b. of the preamble of this final rule, we are finalizing our proposal to create new Pre-MDC MS–DRG 018. In addition, as discussed in section II.E.8.a. of the preamble of this final rule, we are finalizing our proposal to create new Pre-MDC MS–DRG 019.

Comment: Commenters agreed with our proposal to sequence proposed new MS–DRGs 140, 141, and 142 above

proposed new MS–DRGs 143, 144, and 145 and our proposal to sequence proposed new MS–DRGs 143, 144, and 145 above MS–DRGs 135 and 136 in MDC 03.

Response: We thank the commenters for their support. As discussed in section II.E.4. of the preamble of this final rule, we are finalizing our proposal to create new MS–DRGs 140, 141, and 142 and new MS–DRGs 143, 144, and 145.

Comment: Commenters supported our proposal to sequence proposed new MS–DRGs 521 and 522 above MS–DRGs 469 and 470 in MDC 08.

Response: We appreciate the commenters' support. As discussed in section II.E.7.b. of the preamble of this final rule, we are finalizing our proposal to create new MS–DRGs 521 and 522.

Comment: Commenters agreed with our proposal to sequence proposed new MS–DRGs 650 and 651 above MS–DRG 652 (Kidney Transplant) in MDC 11.

Response: We thank the commenters for their support. As discussed in section II.E.8.a. of the preamble of this final rule, we are finalizing our proposal to create new MS–DRGs 650 and 651.

After consideration of the public comments we received, we are finalizing the proposed changes as illustrated in the tables above for the surgical hierarchy within Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 38 for FY 2021.

16. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the CDC National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2021 at a public meeting held on September 10–11, 2019, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 08, 2019.

The Committee held its 2020 meeting on March 17–18, 2020. The deadline for submitting comments on these code proposals was April 17, 2020. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2020 would be included in the October 1, 2020 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A—New Diagnosis Codes, Table 6B—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, and Table 6E—Revised Diagnosis Code Titles for this final rule, which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed or final rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule and this final rule.

Live Webcast recordings of the discussions of the diagnosis and procedure codes at the Committee's September 10–11, 2019 meeting and a recording of the virtual meeting held on March 17–18, 2020 can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the discussions relating to diagnosis codes at the September 10–11, 2019 meeting and March 17–18, 2020 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, attending or participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov.*

Comment: A commenter stated that there was a need to establish and adhere to principles of greater transparency through making coding proposals and revisions public. The commenter also recommended that information be provided to entities that submit similar or related coding requests to enable more efficient and in depth public discussion and that reasonable notice is provided along with timely and accurate agendas when a coding change is accepted for discussion so that key stakeholders are able to participate in public meetings. The commenter also

suggested that clear and timely transcripts or recordings of such meetings should always be made publicly available as well as any written comments that are provided following public meetings so that stakeholders can understand the different perspectives under consideration. According to the commenter, these improvements would allow for timely and knowledgeable participation by experts in the field, enabling CMS staff to have the background and understanding of the current trajectory of treatment options to be reflected in their recommended policies.

Response: As noted earlier in this section, the ICD–10 Coordination and Maintenance Committee is co-chaired by the NCHS/CDC, and CMS. The NCHS has lead responsibility for the ICD–10–CM diagnosis classification while CMS has lead responsibility for the ICD–10–PCS procedure classification. While it is an interdepartmental committee, each organization has their own established processes in responding to requests for coding updates and communicating with the requestors. With regard to the commenter's recommendation that information be provided to entities who submit similar or related coding requests to enable more efficient and in depth public discussion, CMS currently, and has historically informed requestors of similar or related coding requests to provide those requestors with the option and opportunity to collaborate on a joint proposal if they choose to do so. In response to the commenter's recommendation that reasonable notice is provided along with timely and accurate agendas when a coding change (proposal) is accepted for discussion so that key stakeholders are able to participate in public meetings, we note that notice of topics being considered for discussion is provided in an announcement that is published in the **Federal Register** two months in advance of each ICD–10 Coordination and Maintenance Committee meeting. For example, on January 30, 2020, the **Federal Register** Notice announcing the March 17–18, 2020 committee meetings was published with the tentative agenda items listed for both diagnosis and procedure code topics. This notice is located at: *https://www.federalregister.gov/documents/2020/01/30/2020-01756/national-center-for-health-statistics-nchs-icd-10-coordination-and-maintenance-candm-committee.* The agenda is considered tentative leading up to the meeting date as requestors may decide to withdraw their topic request or other topics that were not yet finalized for that specific meeting at the time of the development of the **Federal Register** Notice may subsequently be added to the final agenda. Upon receipt of a procedure code request, CMS immediately acknowledges receipt of the request and communicates to the requestor that additional follow up will occur once an analyst has been assigned. In addition, CMS provides information via Email communication in a letter to each requestor outlining the meeting process and, beginning in 2019, CMS initiated standard pre-meeting conference calls with requestors to discuss their procedure code topic request in more detail in advance of the meeting. Also, prior to the committee meeting, we make the procedure code topic meeting materials publicly available, commonly referred to as the ''Agenda and Handout'' packet on our website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.* Lastly, once the meeting has concluded, CMS sends a follow-up letter to the requestor informing them of next steps in the process so they can anticipate what to expect.

In response to the commenter's recommendation that clear and timely transcripts or recordings of such meetings should always be made publicly available, as well as any written comments that are provided following public meetings so that stakeholders can understand the different perspectives under consideration, we note that we announce during the meeting that a link to the recording (or webcast) will be made publicly available on both the CDC and CMS web pages following the meeting, along with the slides that were presented. This information is generally posted no later than one week following the meeting and additional details regarding each organization's website where materials are posted is also included in our IPPS rule as discussed earlier in this section. With respect to making written comments that are received after the meeting publicly available so that stakeholders can understand different perspectives, we will take that into consideration for the future. We note that some organizations, such as the AHIMA, routinely display the comments they have submitted in response to code proposals on their website. Therefore, in response to the commenter's concern, we believe that the processes we currently have in place enable the CMS staff to have the background and understanding of the current trajectory of treatment options to be considered in our proposed policies.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

Comment: A commenter suggested that CMS consider accelerating the ICD–10 coding timeline for novel indications to address rare and unmet clinical needs, such as expediting the implementation of innovative diagnosis codes for new or emerging therapeutic areas. The commenter provided an example of how the Food and Drug Administration's (FDA's) accelerated approval pathways, such as Breakthrough Designation, play an important role in providing priority review for products that address significant unmet need and have compelling clinical data. According to the commenter, after FDA-approval,

however, patients are often still unable to access these therapies if the disease does not yet have an appropriate ICD–10 diagnosis code. The commenter stated that a lack of accurate ICD–10 coding may delay patient access to treatment as providers engage in the time-consuming process of demonstrating their patients' diagnosis to payers, which the commenter stated typically results in ongoing appeals and exception requests. The commenter stated this is particularly concerning in patient populations with rare diseases experiencing progressive, and oftentimes fatal, conditions.

The commenter acknowledged that CMS may grant implementation exceptions for codes capturing new technology and understands that topics presented during the fall meeting are considered for April 1 implementation if there is a strong and convincing case made by the requester at the Committee's public meeting. However, relying on this rationale, the commenter stated their belief that it is critical to establish a process for expedited assignment of new ICD–10 diagnosis codes for therapeutic areas that have medications under review via an accelerated FDA review. According to the commenter, without timely assignment of ICD–10 diagnosis codes, access to new products may be delayed or denied, and resources appropriated by Congress and used by FDA for its accelerated approval pathways go to waste. The commenter encouraged CMS to revise and update the ICD–10 process to ensure timely access to these innovative products.

Response: As stated earlier in this section, the ICD–10 Coordination and Maintenance Committee meeting is co-chaired by CDC/NCHS and CMS with the CDC/NCHS having lead responsibility for the ICD–10–CM diagnosis classification. Requests for new diagnosis codes must be submitted to *nchsicd10cm@cdc.gov* for consideration. Also, as previously noted, section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year. As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32559), the CDC/NCHS implemented new ICD–10–CM diagnosis codes U07.0 (Vaping-related disorder) and U07.1, (COVID–19) for reporting effective April 1, 2020. Therefore, with respect to the commenter's concerns, we believe there are existing processes in place to implement diagnosis codes in an expedited manner, however, we also encourage the commenter to contact CDC/NCHS directly for additional information and further discussion of any remaining concerns.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting materials and live webcast are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests.

There were not any requests submitted for an expedited April 1, 2020 implementation of a new code at the September 10–11, 2019 Committee meeting. However, as announced by the CDC on December 9, 2019, a new ICD–10 emergency code was established by the World Health Organization (WHO) in response to recent occurrences of vaping related disorders. Consistent with this update, the CDC/NCHS implemented a new ICD–10–CM diagnosis code, U07.0 (Vaping-related disorder) for U.S. reporting of vaping-related disorders effective April 1, 2020. In addition, as announced by the CDC, a new emergency code was established by the WHO on January 31, 2020, in response to the 2019 Novel Coronavirus (2019–nCoV) disease outbreak that was declared a public health emergency of international concern. Consistent with this update, the CDC/NCHS implemented a new ICD–10–CM diagnosis code, U07.1 (COVID–19) for U.S. reporting of the 2019 Novel Coronavirus disease effective April 1, 2020. We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/icd10cm.htm* for additional details regarding the implementation of these new diagnosis codes.

We provided the MS–DRG assignments for these codes effective with discharges on and after April 1, 2020, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code, and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new diagnosis code being assigned to the same MS–DRG as the predecessor code. Effective with discharges on and after April 1, 2020, diagnosis code U07.0 is assigned to MDC 04 (Diseases and Disorders of the Respiratory System) in MS–DRGs 205 and 206 (Other Respiratory System Diagnoses with and without MCC, respectively), consistent with the assignment of the predecessor diagnosis code. Effective with discharges on and after April 1, 2020, diagnosis code U07.1 is assigned to MDC 04 in MS–DRGs 177, 178 and 179

(Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively), MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period) in MS–DRG 791 (Prematurity with Major Problems) and MS–DRG 793 (Full Term Neonate with Major Problems), and MDC 25 (Human Immunodeficiency Virus Infections) in MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively).

These assignments for diagnosis codes U07.0 and U07.1 are reflected in Table 6A- New Diagnosis Codes associated with the proposed rule and this final rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). We also noted that Change Request (CR) 11623, Transmittal 4499, titled ''Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) for Vaping Related Disorder'', was issued on January 24, 2020 (available via the internet on the CMS website at: *https://www.cms.gov/files/document/r4499cp.pdf*) regarding the release of an updated version of the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1, to be effective with discharges on or after April 1, 2020 reflecting new diagnosis code U07.0. The updated software, along with the updated ICD–10 MS–DRG V37.1 Definitions Manual and the Definitions of Medicare Code Edits V37.1 manual was made available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* In response to the implementation of diagnosis code U07.1 (COVID–19), we subsequently released a new updated version of the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1 R1, effective with discharges on or after April 1, 2020 reflecting this new code, which replaced the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1 that reflected diagnosis code U07.0 (Vaping-related disorder). The updated software, along with the updated ICD–10 MS–DRG V37.1 R1 Definitions Manual and the Definitions of Medicare Code Edits V37.1 R1 manual are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In response to the COVID–19 pandemic and new treatments that have followed, on July 30, 2020 we announced the implementation of 12 new ICD–10–PCS procedure codes to identify the introduction or infusion of therapeutics for treating hospital inpatients with COVID–19. These procedure codes will afford the healthcare industry the ability to track the use of these drugs and their effectiveness in the inpatient setting, effective with discharges on and after August 1, 2020. The 12 new ICD–10–PCS procedure codes listed in this section of this rule are designated as non-O.R. and do not affect any MDC or MS–DRG assignment as shown in the following table.

Procedure Code	Description	*O.R.	MDC	MS-DRG
XW013F5	Introduction of other new technology therapeutic substance into subcutaneous tissue, percutaneous approach, new technology group 5	N		
XW033E5	Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5	N		
XW033F5	Introduction of other new technology therapeutic substance into peripheral vein, percutaneous approach, new technology group 5	N		
XW033G5	Introduction of sarilumab into peripheral vein, percutaneous approach, new technology group 5	N		
XW033H5	Introduction of tocilizumab into peripheral vein, percutaneous approach, new technology group 5	N		
XW043E5	Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5	N		
XW043F5	Introduction of other new technology therapeutic substance into central vein, percutaneous approach, new technology group 5	N		
XW043G5	Introduction of sarilumab into central vein, percutaneous approach, new technology group 5	N		
XW043H5	Introduction of tocilizumab into central vein, percutaneous approach, new technology group 5	N		
XW0DXF5	Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5	N		
XW13325	Transfusion of convalescent plasma (nonautologous) into peripheral vein, percutaneous approach, new technology group 5	N		
XW14325	Transfusion of convalescent plasma (nonautologous) into central vein, percutaneous approach, new technology group 5	N		

We also note that Change Request (CR) 11623, Transmittal 10317, titled ''Update to the International Classification of Diseases, Tenth Revision, (ICD–10) Diagnosis Codes for Vaping Related Disorder and Diagnosis and Procedure Codes for the 2019 Novel Coronavirus (COVID–19)'', was issued on August 21, 2020 (available via the internet on the CMS website at: *https://www.cms.gov/files/document/r10317OTN.pdf*)

In response to the implementation of these procedure codes, we subsequently released a new updated version of the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.2, effective with discharges on or after August 1, 2020 reflecting these new codes, which replaced the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1 R1 that reflected diagnosis codes U07.0 (Vaping-related disorder) and U07.1 (COVID–19). The updated software, along with the updated ICD–10 MS–DRG V37.2 Definitions Manual and the Definitions of Medicare Code Edits V37.2 manual are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

ICD–9–CM addendum and code title information is published on the CMS website at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC website at: *http://*

www.cdc.gov/nchs/icd/icd10.htm. Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes coding update information to publishers and software vendors.

The following chart shows the number of ICD–10–CM and ICD–10–PCS codes and code changes since FY 2016 when ICD–10 was implemented.

Total Number of Codes and Changes in Total Number of Codes per Fiscal Year ICD-10-CM and ICD-10-PCS Codes		
Fiscal Year	**Number**	**Change**
FY 2016		
ICD-10-CM	69,823	
ICD-10-PCS	71,974	
FY 2017		
ICD-10-CM	71,486	+1,663
ICD-10-PCS	75,789	+3,815
FY 2018		
ICD-10-CM	71,704	+218
ICD-10-PCS	78,705	+2,916
FY 2019		
ICD-10-CM	71,932	+228
ICD-10-PCS	78,881	+176
FY 2020		
ICD-10-CM	72,184	+252
ICD-10-PCS	77,571	-1,310
FY 2021		
ICD-10-CM	72,616	+432
ICD-10-PCS	78,115	+556

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting.

17. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2021

As discussed in the FY 2021 IPPS/LTCH proposed rule (84 FR 32560 through 32564) for FY 2021, we proposed to delete MS–DRGs 129 and 130, add new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and to reassign a subset of the procedures currently assigned to MS–DRGs 129 and 130 to new MS–DRGs 140 through 142. Additionally, we proposed to create new MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively) and to assign a subset of the procedures currently assigned to MS–DRGs 469 and 470 to new MS–DRGs 521 and 522. (We note that in the proposed rule, we inadvertently referred to these as MS–DRGs 551 and 552.)

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the

list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRGs 129, 130, 469 and 470 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as shown in the table in this section of this rule. Therefore, we proposed that if the applicable MS–DRG changes are finalized, in addition to deleting MS–DRGs 129 and 130, we also would add new MS–DRGs 140, 141, 142, 521 and 522 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit and make conforming changes as reflected in the table. We also proposed to continue to include the existing MS–DRGs currently subject to the policy as also displayed in the table in this section of this rule.

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MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC

MDC	MS-DRG	MS-DRG Title
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement And Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC

MDC	MS-DRG	MS-DRG Title
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

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As discussed in section II.E.5.a. of the preamble of this final rule, we are finalizing our proposal to delete MS–DRGs 129 and 130, add new MS–DRGs 140, 141, and 142, and to reassign a subset of the procedures currently assigned to MS–DRGs 129 and 130 to new MS–DRGs 140 through 142. Additionally, we are finalizing our proposal to create new MS–DRGs 521 and 522 and to reassign a subset of the procedures currently assigned to MS–DRGs 469 and 470 to new MS–DRGs 521 and 522. We did not receive any public comments opposing our proposal to delete MS–DRGs 129 and 130. Additionally, we did not receive any public comments opposing our proposal to add MS–DRGs 140, 141, 142, 521 and 522 to the policy for replaced devices offered without cost or with credit as reflected in the previous table or to continue to include the existing MS–DRGs currently subject to the policy. Therefore, we are finalizing the list of MS–DRGs in the table included in the proposed rule and in this rule that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2020.

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

18. Out of Scope Public Comments Received

We received public comments on MS–DRG related issues that were outside the scope of the proposals included in the FY 2021 IPPS/LTCH PPS proposed rule.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.E.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than November 1, 2020 so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

E. Recalibration of the FY 2021 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2021, we proposed to use two data sources: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2019 MedPAR data used in this final rule include discharges occurring on October 1, 2018, through September 30, 2019, based on bills received by CMS through March 31, 2019, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2019 MedPAR file used in calculating the relative weights includes data for approximately 9,218,950 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2020 update of the FY 2019 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2021 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2021 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2019 MedPAR claims data, grouped through the ICD–10 version of the FY 2021 GROUPER (Version 38).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the March 31, 2020 update of the FY 2018 HCRIS for calculating the FY 2021 cost-based relative weights.

2. Methodology for Calculation of the Relative Weights

a. General

In this final rule, as we proposed, we calculated the FY 2021 relative weights based on 19 CCRs, as we did for FY 2020. The methodology we proposed to use to calculate the FY 2021 MS–DRG cost-based relative weights based on claims data in the FY 2019 MedPAR file and data from the FY 2018 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2021 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2019 MedPAR file.

(Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)

• Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

• Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.

• At least 92.8 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.

• Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.

• Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2020, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2021, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with FY 2020 IPPS/LTCH PPS final rule, we also proposed to include all applicable data from subsection (d) hospitals participating in

the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2018 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file posted via the internet on the CMS website for this final rule and available at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. We stated in the proposed rule that, if we receive comments about the groupings in this supplemental file, we may consider these comments as we finalize our policy. However, we did not receive any comments on the groupings in this table, and therefore, we are finalizing the groupings as proposed.

We invited public comments on our proposals related to recalibration of the FY 2021 relative weights and the changes in relative weights from FY 2020.

Comment: A commenter requested an explanation for the 187 discharge difference in total discharges in Table 7A and Table 7B (proposed Table 7A for Grouper V37 included 9,127,118 discharges, yet proposed Table 7B for Grouper V38 included 9,126,931 discharges).

Response: The discharge difference arises from the proposed modification to our relative weight methodology to account for the clinical trial CAR T-cell therapy cases(85 FR 32566). In the proposed rule's Table 7B, proposed MS–DRG 018 showed only the 116 non-clinical trial discharges for CAR–T cell therapy cases, under the proposed relative weight calculation discussed in the next section. The 187 discharges the commenter referenced were clinical trial CAR T-cell therapy cases, which are not included in the calculation of the average cost for MS–DRG 018. In addition, these cases are not included in calculating the average and percentile lengths of stay data for MS–DRG 018, so they are not included in the number of discharges in Table 7B.

In the proposed rule, we noted that in the FY 2020 IPPS/LTCH PPS final rule, we adopted a temporary one-time measure for FY 2020 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight, and the FY 2020 relative weight would have declined by 20 percent or more from the FY 2019 relative weight, which was maintained at the FY 2018 relative weight. For an MS–DRG meeting this criterion, the FY 2020 relative weight was set equal to the FY 2019 relative weight, which in turn had been set equal to the FY 2018 relative weight (84 FR 42167). For FY 2020, the only MS–DRG meeting this criterion was MS–DRG 215. We invited public comments on the proposed FY 2021 weight for MS–DRG 215 (Other Heart Assist System Implant) as set forth in Table 5 associated with the proposed rule, including comments on whether we should consider a policy under sections 1886(d)(4)(B) and (C) of the Act similar to the measure adopted in the FY 2020 IPPS/LTCH PPS final rule to maintain the FY 2021 relative weight equal to the FY 2020 relative weight for MS–DRG 215, or an alternative approach such as averaging the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

Comment: Commenters supported a policy that would either maintain the FY 2021 relative weight equal to the FY 2020 relative weight for MS–DRG 215, or average the FY 2020 relative weight and the otherwise applicable FY 2021 weight. Commenters stated that heart assist devices are lifesaving devices that are implanted in patients undergoing high risk procedures or are in cardiogenic shock, and that there have been extensive coding changes such that hospitals are still not correctly reporting their costs. Commenters stated that the proposed relative weight would result in a payment that would be significantly below the cost incurred by providers to provide these procedures and could thereby limit access to Medicare beneficiaries. Commenters indicated that CMS had the authority to adjust the relative weights to ensure appropriate payment to providers for heart assist devices.

Some commenters requested that CMS consider this approach in any situation when the relative weight for an MS–DRG is drastically reduced in a given year, particularly when it follows a significant decline in prior years. Some commenters pointed to MS–DRGs 796 (Vaginal Delivery with Sterilization/D&C with MCC) and 933 (Extensive Burns or Full Thickness Burns with MV >96 hrs without Skin Graft), which also have significant decreases relative to FY 2020.

Response: As we indicated in the FY 2018 IPPS/LTCH final rule (82 FR 38103), and in response to similar comments in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41273) and the FY 2020 IPPS/LTCH final rule (84 FR 42167), we do not believe it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data. Nevertheless, after reviewing the comments received and the data used in our ratesetting calculations, we acknowledge an outlier circumstance where the weight for MS–DRG 215 is seeing a significant reduction for each of the 4 years since CMS began using the ICD–10 data in calculating the relative weights. While we would ordinarily consider this weight change to be appropriately driven by the underlying data, given the comments received, and in an abundance of caution because this may be the MS–DRG assigned when a hospital provides temporary right ventricular support for up to 14 days in critical care patients for the treatment of acute right heart failure or decompensation caused by complications related to COVID–19, including pulmonary embolism, we are adopting a temporary one-time measure for FY 2021 for MS–DRG 215. Specifically, we will set the 2021 relative weight for MS–DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

With regard to the commenters who raised concerns about other MS–DRGs with significant reductions relative to FY 2020, the other MS–DRGs are low volume in our claims data, and therefore typically experience a greater degree of year-to-year variation. For example, while MS–DRGs 796 and 933 would have significant decreases relative to FY 2020, those MS–DRGs experienced considerable increases between FY 2019 and FY 2020. We acknowledge the longstanding concerns related to low volume MS–DRGs and will take into consideration the unique issues relating to such MS–DRGs and the stability of their weights for future rulemaking.

Comment: Some commenters requested that CMS adopt a permanent solution to stabilize payment for MS–

DRG 215, in addition to adopting a hold-harmless or blended rate to stabilize the relative weight for MS–DRG 215, effective with discharges beginning October 1, 2020 for FY 2021. Specifically, the commenters suggested that CMS reassign cases reporting procedure code 02HA3RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach) from MS–DRG 215 to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). According to the commenters, these cases are more clinically aligned with MS–DRGs 216, 217, and 218 and this reassignment would improve the long-term stability of the heart assist MS–DRGs including MS–DRG 215. The commenters also noted that reassigning the cases reporting heart assist system procedures performed intraoperatively from MS–DRG 215 into MS–DRGs 216, 217, and 218 in the FY 2021 IPPS/LTCH PPS final rule would be consistent with CMS precedent and authority.

Response: We note that we did not propose any changes to the assignment of heart assist devices and need additional time to fully analyze this request. Therefore, we are not making changes in this final rule to the assignment of cases reporting heart assist system procedures performed intraoperatively, and we will consider this issue in future rulemaking.

b. Relative Weight Calculation for New MS–DRG 018 for CAR T-cell Therapy

As discussed in section II.E.2.b. of this final rule, we proposed, and are finalizing, to create new MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which are currently reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. As discussed in section IV.I. of this final rule, given the high cost of the CAR T-cell product, we proposed, and are finalizing, a differential payment for cases where the CAR T-cell product is provided without cost as part of a clinical trial to ensure that the payment amount for CAR T-cell therapy clinical trial cases appropriately reflects the relative resources required for providing CAR T-cell therapy as part of a clinical trial.

We stated in the proposed rule that we also believe it would be appropriate to modify our existing relative weight methodology to ensure that the relative weight for new MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs. Specifically, we proposed that clinical trial claims that group to new MS–DRG 018 would not be included when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. Consistent with our analysis of the FY 2019 MedPAR claims data as discussed in section IV.I. of this final rule, we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000, which is the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell biological products licensed to treat relapsed/refractory large B-cell lymphoma as of the time of the development of the proposed rule and this final rule. We also proposed to calculate the following adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs and for purposes of budget neutrality and outlier simulations:

- Calculate the average cost for cases to be assigned to new MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to new MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as clinical trial cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Each year, when we calculate the relative weights, we use a transfer-adjusted case count for each MS–DRG, which accounts for payment adjustments resulting from our postacute care transfer policy. This process is described in the FY 2006 IPPS/LTCH PPS final rule (70 FR 47697). We proposed to apply this adjustor to the case count for MS–DRG 018 in a similar manner. We proposed to first calculate the transfer-adjusted case count for MS–DRG 018, and then further adjust the transfer-adjusted case count by the adjustor described previously. Then, we proposed to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Based on the December 2019 update of the FY 2019 MedPAR file, we estimated that the average costs of CAR T-cell therapy cases identified as clinical trial cases were 15% of the average costs of the CAR T-cell therapy cases identified as non-clinical trial cases, and therefore, in calculating the national average cost per case for purposes of the proposed rule, each case identified as a clinical trial case was adjusted to 0.15. We indicated that we expected to recalculate this proposed adjustor for the CAR T cell therapy clinical trial cases for the final rule based on the updated data available. We also noted that we were applying this proposed adjustor for CAR T-cell therapy clinical trial cases for purposes of budget neutrality and outlier simulations, as discussed further in section II.A. of the Addendum to the proposed rule and this final rule.

We invited public comments on our proposal.

Comment: A commenter expressed concern with our methodology to divide cases into clinical trial and non-clinical trial cohorts, stating that both criteria used to identify clinical trial cases, the presence of ICD–10–CM diagnosis code Z00.6 or standardized drug charges of less than $373,000, are problematic given the inconsistency of charging practices for CAR T-cell therapies and the application of ICD–10–CM diagnosis code Z00.6 in all clinical trial cases. This commenter noted that it is possible that some cases were excluded as clinical trial cases when the hospital actually incurred the full cost of the drug. This commenter suggested that these criteria may have resulted in a lower average adjusted cost for non-clinical trial cases below the cost of the drug.

Some commenters also raised issues in the context of the payment adjustment for CAR T-cell clinical trial cases regarding two relatively less frequent scenarios. Commenters stated that when CAR T-cell therapy products are used out of specification (also termed expanded access), hospitals do not incur the cost of the CAR T-cell therapy product, but the claim would not include ICD–10–CM diagnosis code Z00.6 because the case is not part of a clinical trial. Commenters identified an additional scenario, in which the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of another drug, in which case ICD–10–CM diagnosis code Z00.6 would be included on the claim.

Response: We believe that given the available data, our methodology to divide cases into clinical trial and non-clinical trial cohorts provides reasonable estimates on average of the costs for clinical trial and non-clinical trial cases. We note that in the MedPAR data used in the proposed rule, there were only two cases that were flagged as clinical trials that contained drug charges of more than $373,000. The average drug charge of these two cases was less than the average drug charge for all cases that were identified as non-clinical trial cases. Had we instead assumed that these cases were not clinical trial cases for CAR T-cell therapies, and included these two cases in the calculation of the relative weight, the relative weight would have been slightly lower, rather than higher as the commenter suggested. With respect to the concern about hospital charging practices, we reiterate our earlier response that there is nothing that precludes hospitals from setting their drug charges consistent with their CCRs.

In response to commenters who raised issues in the context of the payment adjustment for CAR T-cell clinical trial cases regarding two scenarios, as discussed elsewhere in this final rule, we are adjusting our proposed policy for the payment adjustment for CAR T-cell clinical trial cases to address these scenarios. Similarly, we are adjusting our methodology here such that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases to the extent such cases can be identified in the historical data. To the best of our knowledge there are no claims in the historical data used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

Comment: Some commenters asked whether standardized drug charges included charges for revenue center 891 in addition to charges from revenue centers 025X, 026X, and 63X. Several commenters questioned whether charges for revenue center 891 were included in CMS' calculation of standardized drug charges given that the MedPAR data dictionary seems to indicate that charges from revenue codes 081X–089X are excluded from ratesetting. Commenters stated that it would be incorrect to exclude charges in revenue center 891, since they would include CAR T product charges. Another commenter asked that CMS include claims with charges of greater than $373,000 in revenue center 891 in identifying claims that were not part of a clinical trial. One commenter requested that CMS apply a series of steps to determine whether charges in revenue center 891 were related to CAR T-cell therapy product acquisition.

Response: We appreciate commenters bringing this issue to our attention. We agree with commenters that while revenue centers 081X–089X are typically excluded from ratesetting, charges from revenue center 891 should be included in our calculation of standardized drug charges for MS–DRG 018. Therefore, for cases that group to MS–DRG 018, we will consider the charges reported in revenue center 891 to be related to CAR T-cell therapy product acquisition and include these charges in determining whether the case contains standardized drug charges of at least $373,000 and therefore should be determined to be non-clinical trial case for purposes of this modified relative weight methodology. We note that the same trims used in calculating the standardized drug costs would apply to determine whether or not a given case is determined to be a clinical trial case for purposes of these modifications to the relative weight methodology.

After consideration of public comments received, we are finalizing our proposal to not include claims determined to be clinical trial claims that group to new MS–DRG 018 when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data. We are also finalizing our proposal to calculate the adjustment described above to account for the CAR T-cell therapy cases determined to be clinical trial cases, with the additional refinement of including revenue center 891 in our calculation of standardized drug charges for MS–DRG 018. Applying this finalized methodology, based on the March 2020 update of the FY 2019 MedPAR file, we estimate that the average costs of CAR T-cell therapy cases determined to be clinical trial cases ($46,0662) are 17 percent of the average costs of CAR T cell therapy cases determined to be non-clinical trial cases ($276,042), and therefore, in calculating the national average cost per case for purposes of this final rule, each case identified as a clinical trial case was adjusted to 0.17. We also note that we are applying this finalized adjustor for cases determined to be CAR T-cell therapy clinical trial cases for purposes of budget neutrality and outlier simulations, as discussed further in section II.A. of the Addendum to the this final rule.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2018 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The FY 2021 cost-based relative weights were then normalized by an adjustment factor of 1.819227 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 19 national average CCRs for FY 2021 are as follows:

Group	CCR
Routine Days	0.421
Intensive Days	0.344
Drugs	0.187
Supplies & Equipment	0.297
Implantable Devices	0.293
Inhalation Therapy	0.147
Therapy Services	0.288
Anesthesia	0.071
Labor & Delivery	0.359
Operating Room	0.167
Cardiology	0.094
Cardiac Catheterization	0.1
Laboratory	0.107
Radiology	0.136
MRIs	0.07
CT Scans	0.034
Emergency Room	0.147
Blood and Blood Products	0.271
Other Services	0.343

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We proposed to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2021. Using data from the FY 2019 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2021, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2020 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2020 to FY 2021. The crosswalk table is as follows.

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

After consideration of the comments we received, we are finalizing our proposals, with the modifications for recalibrating the relative weights for FY 2021 for MS–DRG 018 by including the charges reported in revenue center 891 in determining whether the case should be determined to be a non-clinical trial case, and for MS–DRG 215 by setting the relative weight equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

F. Add-On Payments for New Services and Technologies for FY 2021

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and Qualified Infectious Disease Products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d). In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300).

a. New Technology Add On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

a. Overview

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new

technology exceed certain threshold amounts. The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2021 are presented in a data file that is available, along with the other data files associated with the FY 2020 IPPS/LTCH PPS final rule and correction notice, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. However, we refer readers to section II.G.1.a.(2)b. of the preamble of this final rule where we discuss our final policy to apply the proposed threshold value for new MS–DRG 018 in evaluating the cost criterion for the CAR T-cell therapy technologies for purposes of FY 2021 new technology add-on payments.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the final thresholds for applications for new technology add-on payments for FY 2022 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2021 final rule, by clicking on the FY 2021 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We note that, under our final policy discussed in section II.G.1.a.(2).b. of the preamble of this final rule, beginning with FY 2022, we will use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year. In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001 final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

b. Cost Threshold Evaluation for Proposed New MS–DRG Reassignment

In the FY 2021 IPPS/LTCH PPS proposed rule, we made proposals relating to our evaluation of the cost criterion for technologies that are proposed to be assigned to a new MS–DRG (85 FR 32643 and 32644 and 32650 and 32651). We noted that, as we have discussed in prior rulemaking with regard to the potential creation of a new MS–DRG for CAR T-cell therapies (83 FR 41172), if a new MS–DRG for CAR T-cell therapies were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. Section 1886(d)(5)(K)(ix) of the Act requires that, before establishing any add-on payment for a new medical service or technology, the Secretary shall seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology and shall assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. As discussed in previous rulemaking (71 FR 47996), no add-on payment will be made if the new technology is assigned to a DRG that most closely approximates its costs.

In the proposed rule, we referred readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49481 and 49482), where we discussed whether the WATCHMAN® System met the cost criterion for a new technology add-on payment. Specifically, we discussed whether the threshold value associated with a proposed new MS–DRG should be considered in determining whether the applicant meets the cost criterion. We also discussed instances in the past where the coding associated with a new technology application is included in a finalized policy to change one or more MS–DRGs. For example, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53360 through 53362), we described the cost analysis for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft, which was identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). In that same rule, we finalized a change to the assignment of that procedure code, reassigning it from MS–DRGs 252, 253, and 254 to MS–DRGs 237 and 238. Because of that change, we determined that, for FY 2013, in order for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft to meet the cost criteria, it must demonstrate that the average case weighted standardized charge per case exceeded the thresholds for MS–DRGs 237 and 238. We noted that, in that example, MS–DRGs 237 and 238 existed previously; therefore, thresholds that were 75 percent of one standard deviation beyond the geometric mean standardized charge for these MS–DRGs were available to the public in Table 10 at the time the application was submitted. (We note that for fiscal years prior to FY 2020, Table 10 included the cost thresholds used to evaluate applications for new technology add-on payments for the next fiscal year.) We stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24460) that in the case of WATCHMAN® System, if MS–DRGs 273 and 274 were to be finalized for FY 2016, we recognized that thresholds that are 75 percent of one standard deviation beyond the geometric mean standardized charge would not have been available at the time the application was submitted. We stated our belief that it could be appropriate for the applicant to demonstrate that the average case weighted standardized charge per case exceeded these thresholds for MS–DRGs 273 and 274, for which this technology would be reassigned. Accordingly, we made available supplemental threshold values on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech* that were calculated using the data used to generate the FY 2015 IPPS/LTCH PPS Table 10 and reassigned the procedure codes, in accordance with the finalized policies discussed in section II.G.3.b. of the preamble of the FY 2016 IPPS/LTCH PPS final rule.

We also noted that in the FY 2016 IPPS/LTCH PPS proposed rule, we invited public comments on whether considering these supplemental threshold values as part of the cost criterion evaluation for this application was appropriate and also on how to address similar future situations in a broader policy context should they occur. After consideration of the comments, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49482) we stated that we agreed with the commenters that we should evaluate the cost threshold in effect at the time the new

technology add-on payment application is submitted to determine if an applicant exceeds the cost threshold. We stated that we agreed with commenters that this policy is most predictable for applicants. We also stated that we were maintaining our current policy to use the thresholds issued with each final rule for the upcoming fiscal year when making a determination to continue add-on payments for those new technologies that were approved for new technology add-on payments from the prior fiscal year.

In the FY 2021 IPPS/LTCH PPS proposed rule, we noted that at the time of the FY 2016 final rule, in applying this policy, we did not anticipate the onset of new, extremely high cost, technologies such as CAR T-cell therapy, nor such significant variance between the thresholds at the time of application and the thresholds based on the finalized MS–DRG assignment for the upcoming year. For example, in the FY 2016 final rule, the difference between the MS–DRG threshold amount for MS–DRGs 237 ($121,777) and 238 ($87,602) set forth in Table 10 associated with the FY 2015 final rule, and the supplemental MS– DRG threshold amount based on the proposed new MS–DRGs 273 ($95,542) and 274 ($77,230), was $26,235 and $10,372 respectively. By comparison, based on the data file released with the FY 2020 final rule (and corresponding correction notice) for FY 2021 applications, the threshold amount for MS–DRG 016 is $170,573. However, the threshold amount for proposed new MS–DRG 018 (in the data file released with this proposed rule) is $1,237,393, which is more than 7 times greater.

We stated that in light of the development of new technologies, such as CAR T-cell therapies, and the more substantial shifts in the MS–DRG threshold amounts that may result from the reassignment of new technologies for the upcoming fiscal year, we believe it is appropriate to revisit the policy described in the FY 2016 final rule. We stated that while we continue to believe that predictability for applicants is important, we also believe payment accuracy is equally important. We stated our belief that it is necessary to balance predictability with a more accurate evaluation of whether a new technology meets the new technology add-on payment cost criterion by using threshold values that are consistent with how the cases involving the use of the new technology will be paid for in the upcoming fiscal year. We proposed to revise our policy in situations when the procedure coding associated with a new technology application is proposed to be assigned to a proposed new MS–DRG. Specifically, we proposed that effective for FY 2022, for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for a proposed new MS–DRG for the upcoming fiscal year would be used to evaluate the cost criterion for technologies that would be assigned to a proposed new MS–DRG. For example, consider a technology that would be coded using procedure codes assigned to MS–DRG ABC at the time of its application for FY 2022, and then the procedure coding associated with the new technology was proposed to be assigned to a proposed new MS–DRG XYZ in the FY 2022 proposed rule. Instead of using the threshold for MS–DRG ABC based on the data file released with the FY 2021 final rule for FY 2022 applications, we proposed to use the proposed threshold for the newly proposed MS–DRG XYZ based on the data file released with the FY 2022 proposed rule, which would otherwise contain the proposed thresholds for FY 2023 applications. We stated our belief that using the proposed rule thresholds for the proposed new MS–DRG would further promote payment accuracy by using the latest data available to assess how the technology would be paid for in the upcoming fiscal year, if the proposed reassignment to the new MS–DRG was finalized, while also providing the applicant and the public adequate time to analyze whether the technology meets the cost criterion using these proposed thresholds and to provide public comment following the proposed rule.

In the FY 2021 proposed rule, we stated that we believe it is important that the cost criterion be applied in a manner that accurately reflects the anticipated payment for the technology. In assessing the adequacy of the otherwise applicable MS–DRG payment rate for a high cost new technology, where the reassignment of such a technology to a proposed new MS–DRG may result in a substantial change in the MS–DRG threshold amounts, we stated our belief that it is necessary to evaluate that technology using the proposed thresholds for the newly proposed MS–DRG to which the technology would be reassigned.

We also stated that we believe this policy is consistent with section 1886(d)(5)(K)(ix) of the Act which, as previously noted, requires that before establishing any add-on payment for a new medical service or technology, the Secretary seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology, and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. This provision further states that no add-on payment will be made with respect to such new technology. As we have noted in prior rulemaking with regard to the CAR T cell therapies (83 FR 41172), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. For these reasons, we also proposed, for purposes of FY 2021 new technology add-on payments, to evaluate the cost criterion for the CAR T-cell therapy technologies using the proposed threshold for the newly proposed MS–DRG to which the procedure codes describing the use of the CAR T-cell therapies would be assigned in FY 2021 (MS–DRG 018). We noted that this proposed policy would apply to the new FY 2021 CAR T-cell therapy applications, KTE–X19 and Liso-cel, and those CAR T-cell therapies previously approved for new technology add-on payments, KYMRIAH® and YESCARTA® (we note that KTE–X19 and Liso-cel did not meet the July 1 deadline as specified in § 412.87(e)). As discussed in section II.E.2.b. of the preamble of this final rule, we are finalizing our proposal to create a new MS–DRG 018 for cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 for FY 2021.

Comment: We did not receive any comments specifically regarding our proposal that, effective for FY 2022, for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for a proposed new MS–DRG for the upcoming fiscal year would be used to evaluate the cost criterion for technologies that would be assigned to a proposed new MS–DRG. We also did not receive any comments specifically on our proposal to apply this policy, effective for FY 2021, for purposes of evaluating the cost criterion for the CAR–T cell therapy technologies using the proposed threshold for the newly proposed MS–DRG to which the procedure codes describing the use of the CAR–T cell therapies would be assigned in FY 2021 (MS–DRG 018).

Several commenters, who were also applicants for new technology add-on payments for FY 2021, disagreed with

CMS's position that their technologies would not meet the cost criterion based on the MS–DRG 018 threshold amount of $1,237,393. These commenters presented updated cost analyses that they believe demonstrate that the applicant technology meets the cost criterion. One commenter stated that the proposed cost threshold for MS–DRG 018 is inaccurate. Specifically, the commenter believed that $913,244, which CMS cited as the standardized charge per case for DRG 018, is based on the standard deviation charges for those cases, and that the actual average standardized charge per case, according to the FY 2021 Proposed BOR file for Version 38 of the MS–DRGs is $1,387,946.33, which exceeds the cost threshold for MS–DRG 018. This commenter urged CMS to audit its calculations and then reapply the new cost threshold to current new technology add-on payment applicants.

Response: We thank the commenters for their input. We have reviewed the data and agree that we inadvertently used the wrong value for the average case-weighted standardized charge from the FY 2021 Proposed BOR File. The commenter is correct that using the arithmetic mean charge of $1,387,946.33 would exceed the proposed threshold for new MS–DRG 018 of $1,237,393.

We noted in the FY 2021 IPPS/LTCH PPS proposed rule that, if finalized, this policy would apply to the new FY 2021 CAR T-cell therapy applications, KTE–X19 and Liso-cel., and those CAR T-cell therapies previously approved for new technology add-on payments, KYMRIAH® and YESCARTA®. However, we note that neither Kite Pharma (the applicant for KTE–X19) nor Juno Therapeutics, a Bristol-Myers Squibb Company (the applicant for Liso-cel) received FDA approval for their therapies by July 1, and therefore, these technologies were not eligible for consideration for new technology add-on payments for FY 2021. We also note, as discussed later in this rule, that KYMRIAH® and YESCARTA® are no longer considered ''new'' for purposes of new technology add-on payments for FY 2021. Accordingly, we are not applying this policy to evaluate the cost criterion for CAR T-cell therapy technologies using the proposed threshold for MS–DRG 018 to which the procedure codes describing the use of the CAR T-cell therapies will be assigned beginning in FY 2021.

As discussed in the preamble of the proposed rule and this final rule, while we continue to believe that predictability for applicants is important, we also believe payment accuracy is equally important. In order to promote payment accuracy, as previously discussed, and after consideration of the comments received, we are finalizing our proposal to use the proposed threshold for the upcoming fiscal year for any proposed new MS–DRG to evaluate the cost criterion for technologies that would be assigned to the proposed new MS–DRG, beginning with FY 2022 new technology add-on payments for all applicants and previously approved technologies that may continue to receive new technology add-on payments in FY 2022. As we have noted in prior rulemaking with regard to the CAR T cell therapies (83 FR 41172), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

Finally, amidst our work on payment accuracy and coverage for CAR–T, we have heard from stakeholders that cell therapy goes beyond CAR–T to include Tumor-Infiltrating Lymphocyte (TIL) Therapy and Engineered T Cell Receptor (TCR) Therapy. While all of these treatments are autologous, CAR–T is currently limited to liquid tumors, and we foresee the need to address solid tumor treatments such as TIL and TCR in the near future. As the process and decisions on these issues take time, we plan to continue to engage with stakeholders to understand the needs necessary for patients and providers to get appropriate access as quickly as possible to these potentially lifesaving treatments. Our processes continue to evolve as innovative treatments evolve.

c. Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations;

editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS Final Rule (67 FR 50015), although we are affiliated with FDA and we do not question FDA's regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not use FDA criteria to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and efficacy on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

d. Alternative Inpatient New Technology Add-on Payment Pathway

Under § 412.87(c) and (d) of the regulations, beginning with applications for new technology add-on payments for FY 2021, certain transformative new devices and Qualified Infectious Disease Products (QIDPs) may qualify for the new technology add-on payment under an alternative pathway, as described in this section. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for complete discussion on this policy (84 FR 42292 through 42297). We note, in section II.G.9.b. of this preamble, we discuss our final policy to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway. In addition, we are finalizing our policy to refer more broadly to ''certain antimicrobial products'' rather than specifying the particular FDA programs for antimicrobial products (that is, QIDPs and LPADs) that are the subject of the alternative new technology add-on payment pathway. (We refer the reader to section II.G.9.b. of this preamble below for a complete discussion regarding this final policy.) We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS will review the application based on the information provided by the applicant under the alternative pathway specified by the applicant. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. This policy is codified at § 412.87(c). Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program will need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(c)(3), and will be considered new as reflected in § 412.87(c)(2). We note, in section II.G.8. of the preamble of this final rule, we are clarifying our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. (We refer the reader to section II.G.8. of this preamble below for a complete discussion regarding this clarification.)

(2) Alternative Pathway for Qualified Infectious Disease Products (QIDPs)

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We codified this policy at § 412.87(d). Under this alternative pathway for QIDPs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP will need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(d)(3), and will be considered new as reflected in § 412.87(d)(2).

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for complete discussion on this policy (84 FR 42292 through 42297). We note, in section II.G.9.b. of the preamble of this final rule, we are clarifying a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. (We refer the reader to section II.G.9.b. of this preamble below for a complete discussion regarding this clarification.)

e. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning

with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for a medical product designated by FDA as a QIDP) of the estimated costs of the new technology or medical service.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for complete discussion on the increase in the new technology add on payment beginning with discharges on or after October 1, 2019. We note, in section II.G.9.b. of the preamble of this final rule, we discuss our final policy to increase the new technology add-on payment percentage to 75 percent for products approved under FDA's LPAD pathway. (We refer the reader to section II.G.9.b. of this preamble below for a complete discussion regarding this final policy.)

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

f. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. We note, in section II.G.9.c. of the preamble of this final rule, we discuss our finalized process by which a technology for which an application for new technology add-on payments is submitted under the alternative pathway for certain antimicrobial products would receive conditional approval for such payment, provided the product receives FDA marketing authorization by July 1 of the year for which the new technology add-on payment application was submitted. (We refer the reader to section II.G.9.c. of this preamble of this final rule for a complete discussion regarding this final policy.)

g. Council on Technology and Innovation (CTI)

The Council on Technology and Innovation at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS website, in a user friendly format. This guide was published in 2010 and is available on the CMS website at: *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf*.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

h. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2022 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously

described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2022, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347.

As discussed previously, in the FY 2020 IPPS/LTCH PPS final rule, we adopted an alternative inpatient new technology add-on payment pathway for certain transformative new devices and for Qualified Infectious Disease Products, as set forth in the regulations at § 412.87(c) and (d). The change in burden associated with these changes to the new technology add-on payment application process were discussed in a revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347. In accordance with the implementing regulations of the PRA, we detailed the revisions of the ICR and published the required 60-day notice on August 15, 2019 (84 FR 41723) and 30-day notice on December 17, 2019 (84 FR 68936) to solicit public comments. The ICR is currently pending OMB approval.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2021 prior to publication of the FY 2021 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on October 8, 2019 (84 FR 53732), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on December 16, 2019. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2021 new medical service and technology add-on payment applications before the publication of the FY 2021 IPPS/LTCH PPS proposed rule.

We stated in the FY 2021 IPPS/LTCH PPS proposed rule that approximately 100 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the morning and afternoon sessions of the town hall on the CMS YouTube web page at: *https://www.youtube.com/watch?v=4z1AhEuGHqQ* and *https://www.youtube.com/watch?v=m26Xj1EzbIY*, respectively. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of January 3, 2020, in our evaluation of the new technology add-on payment applications for FY 2021 in the development of the FY 2021 IPPS/LTCH PPS proposed rule.

In response to the published notice and the December 16, 2019 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2021 new technology add-on payments. We also noted in the FY 2021 IPPS/LTCH PPS proposed rule that we do not summarize comments that are unrelated to the ''substantial clinical improvement'' criterion. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (84 FR 53732 through 53734), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2021. Therefore, we did not summarize those written comments in the proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.G.5. of the preamble of the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32581 through 32678), we summarized comments regarding individual applications, or, if applicable, indicated that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments

In section II.G.4. of the proposed rule (85 FR 32572 through 32580), we discussed the proposed FY 2021 status of 18 technologies approved for FY 2020 new technology add-on payments. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We refer readers to a table at the end of this section summarizing for FY 2021 the name of each technology, newness start date, whether we are continuing or discontinuing the add-on payment for FY 2021, relevant final rule citations, final maximum add-on payment amount and coding assignments.

a. KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel)

Two manufacturers, Novartis Pharmaceuticals Corporation and Kite Pharma, Inc., submitted separate applications for new technology add-on payments for FY 2019 for KYMRIAH® (tisagenlecleucel) and YESCARTA® (axicabtagene ciloleucel), respectively. Both of these technologies are CD–19-directed T-cell immunotherapies used for the purposes of treating patients with aggressive variants of non-Hodgkin lymphoma (NHL). On May 1, 2018, Novartis Pharmaceuticals Corporation received FDA approval for KYMRIAH®'s second indication, the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. On October 18, 2017, Kite Pharma, Inc. received FDA approval for the use of YESCARTA® indicated for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. With respect to the newness criterion, because potential cases representing patients who may be eligible for treatment using KYMRIAH® and YESCARTA® would group to the same MS–DRGs (because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes are used to report treatment using either KYMRIAH® or YESCARTA®), and because we believed that these technologies are intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, we considered these two technologies to be substantially similar to each other. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41285 through 41286) and FY 2020 IPPS/LTCH/PPS final rule (84 FR 42185 through 42187) for a complete discussion. We stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41285 through 41286) and FY 2020 IPPS/LTCH PPS final rule (84 FR 42185 through 42186) that in accordance with our policy, since we consider the technologies to be substantially similar to each other, it is appropriate to use the earliest market availability date submitted as the beginning of the newness period for both technologies. According to the applicant for YESCARTA®, the first commercial shipment of YESCARTA® was received by a certified treatment center on November 22, 2017. Therefore, based on our policy, with regard to both technologies, we stated that the beginning of the newness period would be November 22, 2017. KYMRIAH® and YESCARTA® were approved for new technology add-on payments for FY 2019 (83 FR 41299). We refer readers to section II.H.5.a. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41283 through 41299) and section II.H.4.d. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42185 through 42187) for a complete discussion of the new technology add-on payment application, coding and payment amount for KYMRIAH® and YESCARTA® for FY 2019 and FY 2020.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for KYMRIAH® and YESCARTA®, as discussed in the FY 2019 IPPS/LTCH PPS final rule, according to the applicant for YESCARTA®, the first commercial shipment of YESCARTA® was received by a certified treatment center on November 22, 2017. As previously stated, we use the earliest market availability date submitted as the beginning of the newness period for both KYMRIAH® and YESCARTA®. Therefore, we consider the beginning of the newness period for both KYMRIAH® and YESCARTA® to commence November 22, 2017. Because the 3-year anniversary date of the entry of the technology onto the U.S. market (November 22, 2020) will occur in the first half of FY 2021, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2021.

Comment: Commenters supported CMS' proposal to discontinue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2021. One commenter expressed support for CMS's proposal to either continue or discontinue new technology add-on payments based on the anniversary date of the product's entry on the market, noting the exception of products that enter the U.S. market in the latter half of the fiscal year.

We also received comments that were not supportive of the proposal. According to these commenters, the removal of new technology add-on payment eligibility for KYMRIAH® and YESCARTA® will widen the gap between therapy cost and reimbursement. According to the commenters, reimbursement provided through a new MS–DRG payment will not fully compensate providers for the extraordinarily high cost of the treatment and the expanding gaps between reimbursement and total cost of care may create barriers to this innovative treatment for Medicare beneficiaries. Another commenter offered that CMS has the authority to extend new technology add-on payments for CAR T-cell products into FY 2021 as the third program year. According to the commenter, although November 22, 2017 was the date the first FDA-approved CAR T-cell product was delivered for use to an approved facility, there were very few facilities even able to conduct these procedures, and of those, several were unwilling to do so due to the high cost of the product and low likelihood of getting paid for it. As such, the commenter indicated that November 22, 2017 is not the date to

most appropriately coincide with when the market was fully formed for CAR T-cell products and procedures, particularly within the Medicare beneficiary patient population. According to the commenter, a more appropriate date to describe when the market was fully formed, consisting of buyers and sellers of CAR T-cell products, was October 1, 2018, with the inclusion of CAR T-cell therapies within MS–DRG 016 for FY 2019. The commenter explained that they believe this date is the more appropriate ''first year'' of new technology add-on payment eligibility under the newness criterion, in which case the third year begins in full with the start of FY 2021. According to the commenter, even if CMS is unwilling or unable to consider this alternate conception of ''market availability'' and adjust the CAR T-cell newness date accordingly, CMS nonetheless retains the authority to simply waive its informal, internal ''six months'' policy and grant new technology add-on payment participation for the entirety of FY 2021 as the third (and final) new technology add-on payment year for KYMRIAH® and YESCARTA®. Another commenter provided support for the extension of the new technology add-on payment to KYMRIAH® and YESCARTA® for another year but suggested that all CAR T-cell product that becomes FDA-approved automatically receive new technology add-on payment as well. Finally, other commenters stated a general support for a continuation of new technology add-on payments for all FDA approved CAR T-cell therapies for FY 2021.

Response: We thank the commenters for their input and suggestions. While we appreciate the commenters' concerns, with regard to the technology's newness, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. Section 412.87(b)(2) states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also states that after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of the section.

With respect to the comment that CMS should consider the date when the market was ''fully formed'' as the start of the newness period, we note that while CMS may consider a documented delay in a technology's availability on the U.S. market in determining when the newness period begins, under our historical policy, we do not consider how frequently the medical service or technology has been used in our determination of newness (70 FR 47349). Similarly, our policy for determining whether to extend new technology add-on payments for a third year generally applies regardless of the claims volume for the technology after the start of the newness period. As discussed in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent.

For these reasons, we do not agree that we should use October 1, 2018 as the start of the newness period or otherwise modify our policy for determining whether to extend new technology add-on payments for a third year in considering whether to continue new technology add-on payments for FY 2021 for KYMRIAH® and YESCARTA®. Therefore, KYMRIAH® and YESCARTA® are no longer considered ''new'' for purposes of new technology add-on payments for FY 2021. We are finalizing our proposal to discontinue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2021.

As discussed in section II.E.2.b. of the preamble of this final rule, currently procedures involving CAR T-cell therapies are identified with ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which became effective October 1, 2017. As discussed in section II.E.2.b. of the preamble of this final rule, we are finalizing our proposal to create a new MS–DRG 018 for cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 for FY 2021. We also refer readers to section II.G.1.a.(2).b. of the preamble of this final rule for a complete discussion of our final policy that, effective for FY 2022, for applications for new technology add-on payments and for previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for the upcoming fiscal year for a proposed new MS–DRG would be used to evaluate the cost criterion for any new technologies that would be assigned to a proposed new MS–DRG. As we also discuss in section II.G.1.a.(2)b. of the preamble of this final rule, in the proposed rule we stated that in light of the significant variance in the threshold amount for proposed new MS–DRG 018 for cases involving CAR T-cell therapies, we proposed to apply this policy in evaluating the CAR T-cell therapy technologies for FY 2021 new technology add-on payments. We stated that this would include both the new FY 2021 CAR T-cell therapy applications and those CAR T-cell therapy technologies previously approved for new technology add-on payments, KYMRIAH® and YESCARTA®. Therefore, in the proposed rule we stated that even if KYMRIAH® and/or YESCARTA® were still considered new and within the 3-year anniversary date of the entry of the technology onto the U.S. market, in determining whether these technologies would continue to be eligible for the new technology add-on payment, we proposed to evaluate whether they meet the cost criterion using the proposed threshold for the proposed new MS–DRG 018 for FY 2021 payment.

Per the applicants' cost analyses in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41291), the final inflated average case-weighted standardized charge per case for KYMRIAH® and YESCARTA® is $39,723 (not including the charges related to the technology) and $118,575 (not including the charges related to the technology), respectively. However, we stated in the proposed rule that we now have cases involving the use of CAR T-cell therapy within the FY 2019 MedPAR data that we believe represent cases that would be eligible for KYMRIAH® and YESCARTA® and which can be used to estimate the average standardized charge per case for purposes of the proposed rule. This charge information from the FY 2019 MedPAR data can be found in the FY 2021 Proposed Before Outliers Removed

(BOR) File (available on the CMS website) for Version 38 of the MS–DRGs. We stated that based on information from the FY 2021 Proposed BOR File for Version 38 of the MS–DRGs, the standardized charge per case for MS–DRG 018 is $913,224. The average case-weighted threshold amount based on the proposed new MS–DRG 018 is $1,237,393. We stated that because this estimated average case-weighted standardized charge per case for KYMRIAH® and YESCARTA® ($913,224) does not exceed the average case-weighted threshold amount for proposed new MS–DRG 018 ($1,237,393), we did not believe that the technology would meet the cost criterion and, as previously stated, proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comment on our proposals.

Comment: According to one commenter, CMS' calculations explained in the proposal may be based on an inappropriate figure. According to the commenter, $913,244 was cited as the standardized charge per case for MS–DRG 018; however, based on a review of information released with the proposed rule, this figure is the standard deviation charges for those cases, rather than the average standardized charge. According to the commenter, the actual average standardized charge per case, according to the FY 2021 Proposed BOR file for Version 38 of the MS–DRGs is $1,387,946.33, which exceeds the cost threshold for MS–DRG 018. The commenter encouraged CMS to re-run its calculations and to clarify this issue and the amounts in the final rule.

Response: We reviewed the data and agree we inadvertently used the wrong value for the average case-weighted standardized charge from the FY 2021 Proposed BOR File. The commenter is correct that using the arithmetic mean charge of $1,387,946.33 would exceed the proposed threshold for new MS–DRG 018 of $1,237,393. As previously noted, KYMRIAH® and YESCARTA® are no longer considered ''new'' for purposes of new technology add-on payments for FY 2021 and therefore, as previously stated, we are finalizing our proposal to discontinue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2021.

b. VYXEOS™ (Daunorubicin and Cytarabine) Liposome for Injection

Jazz Pharmaceuticals, Inc. submitted an application for new technology add-on payments for the VYXEOS™ technology for FY 2019. VYXEOS™ was approved by FDA on August 3, 2017, for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML–MRC). CMS approved VYXEOS™ for new technology add on payments for FY 2019 (83 FR 41299). We refer readers to section II.H.5.b. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41299 through 41305) and section II.H.4.e. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42187 through 42188) for a complete discussion of the new technology add on payment application, coding, and payment amount for VYXEOS™ for FY 2019 and FY 2020.

With regard to the newness criterion for VYXEOS™, we consider the beginning of the newness period to commence when VYXEOS™ was approved by FDA (August 3, 2017). Because the 3-year anniversary date of the entry of the VYXEOS™ onto the U.S. market (August 3, 2020) will occur in FY 2020, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for VYXEOS™ for FY 2021.

Comment: A commenter supported CMS' proposal to discontinue new technology add-on payments for VYXEOS™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for VYXEOS™ for FY 2021.

c. VABOMERE™ (Meropenem and Vaborbactam)

Melinta Therapeutics, Inc., submitted an application for new technology add-on payments for VABOMERE™ for FY 2019. VABOMERE™ is indicated for use in the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis caused by designated susceptible bacteria. VABOMERE™ received FDA approval on August 29, 2017 and was approved for new technology add on payments for FY 2019 (83 FR 41311). We refer readers to section II.H.5.c. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41305 through 41311) and section II.H.4.f. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42188 through 42189) for a complete discussion of the new technology add on payment application, coding, and payment amount for VABOMERE™ for FY 2019 and FY 2020.

With regard to the newness criterion for VABOMERE™, we consider the beginning of the newness period to commence when VABOMERE™ received FDA approval (August 29, 2017). Because the 3-year anniversary date of the entry of VABOMERE™ onto the U.S. market (August 29, 2020) will occur in FY 2020, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for VABOMERE™ for FY 2021.

Comment: Several commenters, including the applicant, did not support CMS' proposal to discontinue new technology add-on payments for FY 2021 for VABOMERE™. Commenters highlighted the global health crisis of antimicrobial resistance and corresponding importance of add-on payments for maintaining adequate patient access to novel antibiotics that are effective against multidrug resistant gram-negative bacteria. Some commenters acknowledged the infrequent use of VABOMERE™ due to antibiotic stewardship considerations, but nonetheless expressed concern about the cost burden of novel agents like VABOMERE™ in light of limited treatment options. A few commenters urged CMS to consider the data limitations regarding the infrequent use of novel antibiotics and their dispersion across many MS–DRGs as justification for continuing add-on payments for VABOMERE™ for purposes of additional data collection and further opportunity for relevant MS–DRGs to adjust to the availability of VABOMERE™. A commenter, who is also the applicant, suggested that without appropriate reimbursement for novel antibiotics, such as VABOMERE™, it is unlikely that manufacturers will continue investing in these vitally necessary products.

Several commenters described what they asserted was the particular value of VABOMERE™ during the current public health emergency, as extended hospital stays and prolonged ventilator use for many COVID–19 patients can increase the risk of multidrug resistant bacterial infections. A commenter, who is also the applicant, suggested that CMS employ all of the tools within its authority to address the unprecedented financial challenges health care providers are facing as a result of the economic crisis caused by the COVID–19 pandemic and ensuing public health emergency, including, at a minimum, ensuring eligibility continues for the maximum period of time permitted by statute (currently, a full three years) for

qualified infectious disease products (QIDPs), including VABOMERE™. The applicant also encouraged CMS to implement a DRG carve-out policy for QIDPs that would provide for payment of QIDPs at 100 percent of ASP under the IPPS, which it asserted would improve the balance of incentives for providers who are treating patients with resistant infections, maintain the sustainability of companies that develop and commercialize QIDPs, as well as spur innovation in this critically important area affecting clinical outcomes and public health.

Response: We thank the commenters for their comments. While we appreciate the commenters' concerns, with regard to the technology's newness, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. Section 412.87(b)(2) states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also states that after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of the section.

In addition, and as discussed in the FY 2006 IPPS final rule (70 FR 47349), we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population, or how many MS–DRGs the technology may be spread across. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent. Additionally, we did not propose any policies relating to a DRG carve-out for QIDPs but appreciate the commenter's suggestion.

Based on the reasons stated above, VABOMERE™ is no longer considered ''new'' for purposes of new technology add-on payments for FY 2021. We are finalizing our proposal to discontinue new technology add-on payments for VABOMERE™ for FY 2021.

d. remedē® System

Respicardia, Inc. submitted an application for new technology add-on payments for the remedē® System for FY 2019. The remedē® System is indicated for use as a transvenous phrenic nerve stimulator in the treatment of adult patients who have been diagnosed with moderate to severe central sleep apnea (CSA). On October 6, 2017, the remedē® System was approved by FDA. The remedē® System was approved for new technology add on payments for FY 2019. We refer readers to section II.H.5.d. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41311 through 41320) and section II.H.4.g. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42189 through 42190) for a complete discussion of the new technology add on payment application, coding and payment amount for the remedē® System for FY 2019 and FY 2020.

With regard to the newness criterion for the remedē® System, as we have discussed in prior rulemaking, we consider the beginning of the newness period to commence when the remedē® System was approved by FDA on October 6, 2017. However, as we summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42189 through 42190), a commenter on the FY 2020 IPPS/LTCH PPS proposed rule, who was also the applicant, believed that the newness period for the remedē® System should start on February 1, 2018, instead of the FDA approval date of October 6, 2017. The commenter stated that due to the required build out of operational and commercial capabilities, the remedē® System was not commercially available upon FDA approval and the first case involving its use did not occur until February 1, 2018. The commenter asserted that the date of the first implant should mark the start of the newness period since before that, the technology was not commercially available. In response to that comment, we indicated that we would consider the additional information the applicant provided when proposing whether to continue new technology add-on payments for the remedē® System for FY 2021.

As we have discussed in prior rulemaking (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. With regard to the commenter's assertion that the date of the first implant should mark the start of the newness period, we note that while we may consider a documented delay in a technology's availability on the U.S. market in determining when the newness period begins, under our historical policy, we do not consider how frequently the medical service or technology has been used in our determination of newness (70 FR 47349). As we discussed in the proposed rule, without additional information from the applicant, we cannot determine a newness date based on such a documented delay in commercial availability (and not the first case involving use of the remedē® System on February 1, 2018). However, even if we were to consider the newness period to commence on February 1, 2018, as recommended by the commenter, such that the 3-year anniversary date of the entry of the remedē® System onto the U.S. market would be February 1, 2021 rather than October 6, 2020, that 3-year anniversary date would still occur within the first half of FY 2021. Because the 3-year anniversary date of the entry of the remedē® System onto the U.S. market will occur in the first half of FY 2021, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for the remedē® System for FY 2021.

Comment: A commenter supported CMS' proposal to discontinue new technology add-on payments for FY 2021 for the remedē® System.

Response: We appreciate the commenter's support.

Comment: A commenter did not support CMS' proposal to discontinue new technology add-on payments for FY 2021 for the remedē® System. The commenter, who was also the applicant, requested that CMS extend for one additional year all new technology add-on payments set to expire at the end of FY 2020 due to the extraordinary circumstances of the COVID–19 public health emergency. They expressed concerns that the public health emergency dramatically limited availability of the remedē® System since March 2020, when most elective procedures were halted across the United States. The commenter stated that the reduced access to new technologies for Medicare beneficiaries should be factored into consideration of the newness period expiration date.

Response: We thank the commenter for their comments. While we appreciate the commenter's concerns, with regard to the technology's

newness, as discussed in the FY 2005 IPPS final rule (69 FR 49003), the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available. Section 412.87(b)(2) states that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). Section 412.87(b)(2) also states that after CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of the section. In addition, CMS's policy for determining whether to extend new technology add-on payments for a third year generally applies regardless of the claims volume for the technology. As discussed in the FY 2006 IPPS final rule (70 FR 47349) and earlier in this section, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent.

Based on the reasons stated above, the remedē® System is no longer considered ''new'' for purposes of new technology add-on payments for FY 2021. We are finalizing our proposal to discontinue new technology add-on payments for the remedē® System for FY 2021.

e. ZEMDRI™ (Plazomicin)

Achaogen, Inc. submitted an application for new technology add-on payments for ZEMDRI™ (plazomicin) for FY 2019. According to the applicant, ZEMDRI™ is a next generation aminoglycoside antibiotic, which has been found in vitro to have enhanced activity against many multidrug resistant (MDR) gram-negative bacteria. The applicant received approval from FDA on June 25, 2018, for use in the treatment of adults who have been diagnosed with cUTIs, including pyelonephritis. ZEMDRI™ was approved for new technology add on payments for FY 2019 (83 FR 41334). We refer readers to section II.H.5.f. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41326 through 41334) and section II.H.4.h. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42190 through 42191) for a complete discussion of the new technology add on payment application, coding and payment amount for ZEMDRI™ for FY 2019 and FY 2020.

With regard to the newness criterion for ZEMDRI™, we consider the beginning of the newness period to commence when ZEMDRI™ was approved by FDA on June 25, 2018. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of ZEMDRI™ onto the U.S. market (June 25, 2021) will occur in the second half of FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment amount for a case involving the use of ZEMDRI™ would remain at $4,083.75 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for ZEMDRI™). Cases involving ZEMDRI™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033G4 (Introduction of Plazomicin anti-infective into peripheral vein, percutaneous approach, new technology group 4) or XW043G4 (Introduction of Plazomicin antiinfective into central vein, percutaneous approach, new technology group 4). We invited public comments on our proposal to continue new technology add-on payments for ZEMDRI™ for FY 2021.

Comment: A commenter supported CMS' proposal to continue new technology add-on payments for ZEMDRI™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for ZEMDRI™ for FY 2021. The maximum new technology add-on payment amount for a case involving the use of ZEMDRI™ will remain at $4,083.75 for FY 2021; that is, 75 percent of the average cost of the technology.

f. GIAPREZA™ (angiotensin II)

The La Jolla Pharmaceutical Company submitted an application for new technology add-on payments for GIAPREZA™ for FY 2019. GIAPREZA™, a synthetic human angiotensin II, is administered through intravenous infusion to raise blood pressure in adult patients who have been diagnosed with septic or other distributive shock. GIAPREZA™ was granted a Priority Review designation under FDA's expedited program and received FDA approval on December 21, 2017, for the use in the treatment of adults who have been diagnosed with septic or other distributive shock as an intravenous infusion to increase blood pressure. GIAPREZA™ was approved for new technology add on payments for FY 2019 (83 FR 41342). We refer readers to section II.H.5.g. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41334 through 41342) and section II.H.4.i. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42191) for a complete discussion of the new technology add on payment application, coding and payment amount for GIAPREZA™ for FY 2019 and FY 2020.

With regard to the newness criterion for GIAPREZA™, we consider the beginning of the newness period to commence when GIAPREZA™ was approved by FDA (December 21, 2017). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of GIAPREZA™ onto the U.S. market (December 21, 2020) will occur in the first half of FY 2021, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for GIAPREZA™ for FY 2021.

Comment: A commenter supported CMS' proposal to discontinue new technology add-on payments for GIAPREZA™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for GIAPREZA™ for FY 2021.

g. Cerebral Protection System (Sentinel® Cerebral Protection System)

Claret Medical, Inc. submitted an application for new technology add-on

payments for the Cerebral Protection System (Sentinel® Cerebral Protection System) for FY 2019. According to the applicant, the Sentinel Cerebral Protection System is indicated for the use as an embolic protection (EP) device to capture and remove thrombus and debris while performing transcatheter aortic valve replacement (TAVR) procedures. The device is percutaneously delivered via the right radial artery and is removed upon completion of the TAVR procedure. The De Novo request for the Sentinel® Cerebral Protection System was granted by FDA on June 1, 2017. The Sentinel Cerebral Protection System was approved for new technology add on payments for FY 2019 (83 FR 41348). We refer readers to section II.H.5.h. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41342 through 41348) and section II.H.4.j. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42191 through 42192) for a complete discussion the new technology add on payment application, coding, and payment amount for the Sentinel® Cerebral Protection System for FY 2019 and FY 2020.

With regard to the newness criterion for the Sentinel® Cerebral Protection System, we consider the beginning of the newness period to commence when FDA granted the De Novo request for the Sentinel® Cerebral Protection System (June 1, 2017). Because the 3-year anniversary date of the entry of the Sentinel® Cerebral Protection System onto the U.S. market (June 1, 2020) will occur in FY 2020, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2021.

Comment: A commenter supported CMS' proposal to discontinue new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2021.

h. The AQUABEAM System (Aquablation)

PROCEPT BioRobotics Corporation submitted an application for new technology add-on payments for the AQUABEAM System (Aquablation) for FY 2019. According to the applicant, the AQUABEAM System is indicated for the use in the treatment of patients experiencing lower urinary tract symptoms caused by a diagnosis of benign prostatic hyperplasia (BPH). FDA granted the AQUABEAM System's De Novo request on December 21, 2017, for use in the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. The AQUABEAM System was approved for new technology add on payments for FY 2019 (83 FR 41355). We refer readers to section II.H.5.i. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41348 through 41355) and section II.H.4.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42192 through 42193) for a complete discussion of the new technology add on payment application, coding, and payment for the AQUABEAM System for FY 2019 and FY 2020.

With regard to the newness criterion for the AQUABEAM System, we consider the beginning of the newness period to commence on the date FDA granted the De Novo request (December 21, 2017). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the AQUABEAM System onto the U.S. market (December 21, 2020) will occur in the first half of FY 2021, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for the AQUABEAM System for FY 2021.

Comment: A commenter supported CMS' proposal to discontinue new technology add-on payments for the AQUABEAM System for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the AQUABEAM System for FY 2021.

i. AndexXa™ (coagulation factor Xa (recombinant), inactivated-zhzo)

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2019 for the use of AndexXa™ (coagulation factor Xa (recombinant), inactivated-zhzo). AndexXa™ received FDA approval on May 3, 2018, and is indicated for use in the treatment of patients who are receiving treatment with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. AndexXa™ was approved for new technology add on payments for FY 2019 (83 FR 41362). We refer readers to section II.H.5.j. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41355 through 41362) and section II.H.4.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42193 through 42194) for a complete discussion of the new technology add on payment application, coding, and payment amount for AndexXa™ for FY 2019 and FY 2020.

With regard to the newness criterion for AndexXa™, we consider the beginning of the newness period to commence when AndexXa™ received FDA approval (May 3, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of AndexXa™ onto the U.S. market (May 3, 2021) will occur in the second half of FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving AndexXa™ would remain at $18,281.25 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for AndexXa™). Cases involving the use of AndexXa™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW03372 (Introduction of inactivated coagulation factor Xa into peripheral vein, percutaneous approach, new technology group 2) or XW04372 (Introduction of inactivated coagulation factor Xa into central vein, percutaneous approach, new technology group 2). We invited public comments on our proposal to continue new technology add-on payments for AndexXa™ for FY 2021.

Comment: Several commenters, including the applicant, supported CMS' proposal to continue new technology add-on payments for FY 2021 for AndexXa™.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for AndexXa™ for FY 2021. The maximum new technology

add-on payment amount for a case involving AndexXa™ will remain at $18,281.25 for FY 2021; that is, 65 percent of the average cost of the technology.

j. AZEDRA® (iobenguane Iodine-131) Solution

Progenics Pharmaceuticals, Inc. submitted an application for new technology add-on payments for AZEDRA® (iobenguane Iodine-131) for FY 2020. AZEDRA® is a drug solution formulated for intravenous (IV) use in the treatment of patients who have been diagnosed with obenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma (PPGL). AZEDRA was approved by FDA on July 30, 2018, as a radioactive therapeutic agent indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. AZEDRA® was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.a. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42194 through 42201) for a complete discussion of the new technology add on payment application, coding and payment amount for AZEDRA® for FY 2020.

With regard to the newness criterion for AZEDRA®, we consider the beginning of the newness period to commence when AZEDRA® was approved by FDA (July 30, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of AZEDRA® onto the U.S. market (July 30, 2021) will occur in the second half of FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving AZEDRA® would remain at $98,150 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for AZEDRA®). Cases involving the use of AZEDRA® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033S5 (Introduction of Iobenguane I–131 antineoplastic into peripheral vein, percutaneous approach, new technology group 5), and XW043S5 (Introduction of Iobenguane I–131 antineoplastic into central vein, percutaneous approach, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for AZEDRA® for FY 2021.

Comment: Several commenters supported CMS' proposal to continue new technology add-on payments for FY 2021 for AZEDRA®.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for AZEDRA® for FY 2021. The maximum new technology add-on payment amount for a case involving AZEDRA® will remain at $98,150.00 for FY 2021; that is, 65 percent of the average cost of the technology.

k. CABLIVI® (caplacizumab-yhdp)

The Sanofi Company submitted an application for new technology add-on payments for CABLIVI® (caplacizumab-yhdp) for FY 2020. The applicant described CABLIVI® as a humanized bivalent nanobody consisting of two identical building blocks joined by a tri alanine linker, which is administered through intravenous and subcutaneous injection to inhibit microclot formation in adult patients who have been diagnosed with acquired thrombotic thrombocytopenic purpura (aTTP). CABLIVI® received FDA approval on February 6, 2019, for the treatment of adult patients with acquired aTTP, in combination with plasma exchange and immunosuppressive therapy. CABLIVI® was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.b. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42201 through 42208) for a complete discussion of the new technology add on payment application, coding, and payment amount for CABLIVI® for FY2020.

With regard to the newness criterion for CABLIVI®, we consider the beginning of the newness period to commence when CABLIVI® was approved by FDA (February 6, 2019). Because the 3-year anniversary date of the entry of CABLIVI® onto the U.S. market (February 6, 2022) will occur after FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving CABLIVI® would remain at $33,215 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for CABLIVI®). Cases involving the use of CABLIVI® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW013W5 (Introduction of Caplacizumab into subcutaneous tissue, percutaneous approach, new technology group 5), XW033W5 (Introduction of Caplacizumab into peripheral vein, percutaneous approach, new technology group 5) and XW043W5 (Introduction of Caplacizumab into central vein, percutaneous approach, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for CABLIVI® for FY 2021.

Comment: A commenter supported CMS' proposal to continue new technology add-on payments for CABLIVI® for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for CABLIVI® for FY 2021. The maximum new technology add-on payment amount for a case involving CABLIVI® will remain at $33,215 for FY 2021; that is, 65 percent of the average cost of the technology.

l. ELZONRIS™ (tagraxofusp-erzs)

Stemline Therapeutics submitted an application for new technology add-on payments for ELZONRIS™ for FY 2020. ELZONRIS™ (tagraxofusp-erzs) is a targeted therapy for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) administered via infusion. On December 21, 2018, FDA approved ELZONRIS™ for the treatment of blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients 2 years old and older. ELZONRIS™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.e. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231 through 42237) for a complete discussion of the new technology add on payment application, coding and payment amount for ELZONRIS™ for FY 2020.

With regard to the newness criterion for ELZONRIS™, we consider the beginning of the newness period to commence when ELZONRIS™ was approved by FDA (December 21, 2018). Because the 3-year anniversary date of the entry of ELZONRIS™ onto the U.S. market (December 21, 2021) will occur after FY 2021, we proposed to continue new technology add-on payments for

this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving ELZONRIS™ would remain at $125,448.05 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for ELZONRIS™). Cases involving the use of ELZONRIS™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033Q5 (Introduction of Tagraxofusp-erzs antineoplastic into peripheral vein, percutaneous approach, new technology, group 5) and XW043Q5 (Introduction of Tagraxofusp-erzs antineoplastic into central vein, percutaneous approach, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for ELZONRIS™ for FY 2021.

Comment: A commenter supported CMS' proposal to continue new technology add-on payments for ELZONRIS™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for ELZONRIS™ for FY 2021. The maximum new technology add-on payment amount for a case involving ELZONRIS™ will remain at $125,448.05 for FY 2021; that is, 65 percent of the average cost of the technology.

m. Balversa™ (Erdafitinib)

Johnson & Johnson Health Care Systems, Inc. (on behalf of Janssen Oncology, Inc.) submitted an application for new technology add-on payments for Balversa™ for FY 2020. Balversa™ is indicated for the second line treatment of adult patients who have been diagnosed with locally advanced or metastatic urothelial carcinoma whose tumors exhibit certain fibroblast growth factor receptor (FGFR) genetic alterations as detected by an FDA-approved test, and who have disease progression during or following at least one line of prior chemotherapy including within 12 months of neoadjuvant or adjuvant chemotherapy. Balversa™ received FDA approval on April 12, 2019. Balversa™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.f. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42237 through 42242) for a complete discussion of the new technology add on payment application, coding and payment amount for Balversa™ for FY 2020.

With regard to the newness criterion for Balversa™, we consider the beginning of the newness period to commence when Balversa™ was approved by FDA (April 12, 2019). Because the 3-year anniversary date of the entry of Balversa™ onto the U.S. market (April 12, 2022) will occur after FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving Balversa™ would remain at $3,563.23 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for Balversa™). Cases involving the use of Balversa™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW0DXL5 (Introduction of Erdafitinib antineoplastic into mouth and pharynx, external approach, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for Balversa™ for FY 2021.

Comment: A commenter supported CMS' proposal to continue new technology add-on payments for Balversa™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for Balversa™ for FY 2021. The maximum new technology add-on payment amount for a case involving Balversa™ will remain at $3,563.23 for FY 2021; that is, 65 percent of the average cost of the technology.

n. ERLEADA™ (Apalutamide)

Johnson & Johnson Health Care Systems Inc., on behalf of Janssen Products, LP, Inc., submitted an application for new technology add-on payments for ERLEADA™ (apalutamide) for FY 2020. This oral drug is an androgen receptor inhibitor approved by FDA on February 14, 2018, for the treatment of patients who have been diagnosed with non-metastatic castration-resistant prostate cancer (nmCRPC). ERLEADA™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.g. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42242 through 42247) for a complete discussion of the new technology add on payment application, coding and payment amount for ERLEADA™ for FY 2020.

With regard to the newness criterion for ERLEADA™, we consider the beginning of the newness period to commence when ERLEADA™ was approved by FDA (February 14, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of ERLEADA™ onto the U.S. market (February 14, 2021) will occur in the first half of FY 2021, we proposed to discontinue new technology add-on payments for this technology for FY 2021. We invited public comments on our proposal to discontinue new technology add-on payments for ERLEADA™ for FY 2021.

Comment: A commenter supported CMS' proposal to discontinue new technology add-on payments for ERLEADA™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for ERLEADA™ for FY 2021.

o. SPRAVATO™ (Esketamine)

Johnson & Johnson Health Care Systems, Inc., on behalf of Janssen Pharmaceuticals, Inc., submitted an application for new technology add-on payments for SPRAVATO™ (Esketamine) nasal spray for FY 2020. The FDA-approved indication for SPRAVATO™ is treatment resistant depression (TRD). SPRAVATO™ Nasal Spray was approved by FDA March 5, 2019. SPRAVATO™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.h. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42247 through 42256) for a complete discussion of the new technology add on payment application, coding and payment amount for SPRAVATO™ for FY 2020.

With regard to the newness criterion for SPRAVATO™, we consider the beginning of the newness period to commence when SPRAVATO™ was approved by FDA (March 5, 2019). Because the 3-year anniversary date of the entry of SPRAVATO™ onto the U.S. market (March 5, 2022) will occur after FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-

on payment for a case involving SPRAVATO™ would remain at $1,014.79 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for SPRAVATO™).

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19329), we noted that the applicant had submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for a unique ICD–10–PCS procedure code to specifically identify cases involving the use of SPRAVATO™, beginning in FY 2020. As of the time of the development of the FY 2020 IPPS/LTCH PPS final rule, a unique ICD–10–PCS procedure code to specifically identify cases involving the use of SPRAVATO™ had not yet been finalized in response to the applicant's request. Therefore, we stated that cases reporting SPRAVATO™ would be identified by ICD–10–PCS procedure code 3E097GC (Introduction of other therapeutic substance into nose, via natural or artificial opening) for FY 2020. Subsequent to the FY 2020 IPPS/LTCH PPS final rule, a unique ICD–10–PCS procedure code to specifically identify cases involving the use of SPRAVATO™ was finalized, effective October 1, 2020. As a result, cases involving the use of SPRAVATO™ that are eligible for new technology add-on payments would be identified by ICD–10–PCS procedure code XW097M5 (Introduction of Esketamine Hydrochloride into nose, via natural or artificial opening, new technology group 5) for FY 2021. Because new ICD–10–PCS procedure code XW097M5 is not effective until October 1, 2020, ICD–10–PCS procedure code 3E097GC is the only code available to report the use of the SPRAVATO™ for FY 2020. For FY 2021, beginning with discharges on or after October 1, 2020, cases involving SPRAVATO™ that are eligible for new technology add-on payments will be identified using the new ICD–10–PCS procedure code XW097M5 (that is effective for FY 2021). We invited public comments on our proposal to continue new technology add-on payments for SPRAVATO™ for FY 2021.

Comment: A commenter supported CMS' proposal to continue new technology add-on payments for SPRAVATO™ for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for SPRAVATO™ for FY 2021. The maximum new technology add-on payment amount for a case involving SPRAVATO™ will remain at $1,014.79 for FY 2021; that is, 65 percent of the average cost of the technology.

p. XOSPATA® (gilteritinib)

Astellas Pharma U.S., Inc. submitted an application for new technology add-on payments for XOSPATA® (gilteritinib) for FY 2020. XOSPATA® received FDA approval November 28, 2018 and is indicated for the treatment of adult patients who have been diagnosed with relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA approved test. XOSPATA® was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.i. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42256 through 42260) for a complete discussion of the new technology add on payment application, coding and payment amount for XOSPATA®.

With regard to the newness criterion for XOSPATA®, we consider the beginning of the newness period to commence when XOSPATA® was approved by FDA (November 28, 2018). Because the 3-year anniversary date of the entry of XOSPATA® onto the U.S. market (November 28, 2021) will occur after FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving XOSPATA® would remain at $7,312.50 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for XOSPATA®). Cases involving the use of XOSPATA® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW0DXV5 (Introduction of Gilteritinib antineoplastic into mouth and pharynx, external approach, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for XOSPATA® for FY 2021.

Comment: A commenter supported CMS' proposal to continue new technology add-on payments for XOSPATA® for FY 2021.

Response: We appreciate the commenter's support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for XOSPATA® for FY 2021. The maximum new technology add-on payment amount for a case involving XOSPATA® will remain at $7,312.50 for FY 2021; that is, 65 percent of the average cost of the technology.

q. JAKAFI™ (ruxolitinib)

Incyte Corporation submitted an application for new technology add-on payments for JAKAFI™ (ruxolitinib) for FY 2020. According to the applicant, JAK inhibition represents a therapeutic approach for the treatment of acute graft-versus-host disease (aGVHD) in patients who have had an inadequate response to corticosteroids. JAKAFI™ received FDA approval on May 24, 2019 for the treatment of steroid-refractory aGVHD in adult and pediatric patients 12 years and older. JAKAFI™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42265 through 42273) for a complete discussion of the new technology add on payment application, coding and payment amount for JAKAFI™ for FY 2020.

With regard to the newness criterion for JAKAFI™, we consider the beginning of the newness period to commence when JAKAFI™ was approved by FDA (May 24, 2019). Because the 3-year anniversary date of the entry of JAKAFI™ onto the U.S. market (May 24, 2022) will occur after FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving JAKAFI™ would remain at $3,977.06 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for JAKAFI™). Cases involving the use of JAKAFI™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW0DXT5 (Introduction of Ruxolitinib into mouth and pharynx, external approach, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for JAKAFI™ for FY 2021.

Comment: Several commenters supported our proposal to continue new technology add-on payments for JAKAFI™ for FY 2021.

One commenter, who was also the applicant, presented results from a randomized, open-label, multicenter, Phase 3 REACH 2 study comparing ruxolitinib (JAKAFI™) with the investigator's choice of therapy in patients with steroid-refractory Grade II–IV aGVHD. The applicant stated that these results were published in May

2020 and reinforced findings from the previously reported Phase 2 REACH1 study. The applicant noted that the REACH2 study met its primary endpoint of overall response rate (ORR) at Day 28 with ruxolitinib treatment (62.3% [96/154]) compared to control therapy (39.4% [61/155]) and that no new safety signals were observed. According to the applicant, the most common adverse events up to Day 28 seen with JAKAFI™ were thrombocytopenia, anemia, and cytomegalovirus infection. The applicant concluded that these data further support CMS' assessment that JAKAFI™ met the substantial clinical improvement criterion in FY 2020.

The same commenter provided updated cost information and requested that we revise the maximum add-on payment amount for JAKAFI™ to account for an increase in the Wholesale Acquisition Cost, which is currently $13,504 per 60 tablets. The commenter stated that per the FY 2020 IPPS final rule, CMS calculated the maximum new technology add-on payment using the WAC for 60 JAKAFI™ tablets, determining the per tablet amount, multiplying that figure by two (as JAKAFI™ is taken twice daily), and using a 14 day anticipated duration. Under this methodology, the average cost of JAKAFI™ per case would change from $6,118.56 to $6,301.86 ($13,504/60 * 2 * 14), and limiting the maximum add-on payment to the lesser of 65% of the cost of the technology or 65% of the amount by which the costs of the case exceed the MS–DRG payment would result in a maximum payment of $4,096.21 for JAKAFI™ for FY 2021.

Response: We appreciate the commenters' support and the updated cost information submitted by the applicant.

After consideration of the public comments we received, we are finalizing our proposal, with modification, to continue new technology add-on payments for JAKAFI ™ for FY 2021. Based on the applicant's updated cost information, the maximum new technology add-on payment for a case involving the use of JAKAFI™ is $4,096.21 for FY 2021; that is, 65 percent of the average cost of the technology.

r. T2Bacteria® Panel (T2Bacteria Test Panel)

T2Biosystems, Inc. submitted an application for new technology add-on payments for the T2Bacteria Test Panel (T2Bacteria® Panel) for FY 2020. The T2Bacteria® Panel received 510(k) clearance from FDA on May 24, 2018 for use as an aid in the diagnosis of bacteremia, bacterial presence in the blood, which is a precursor for sepsis. Per the FDA-cleared indication, results from the T2Bacteria® Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions in patients with suspected bacteremia. Concomitant blood cultures are necessary to recover organisms for susceptibility testing or further identification, and for organisms not detected by the T2Bacteria® Panel. The T2Bacteria® Panel was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.m. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42278 through 42288) for a complete discussion of the new technology add on payment application, coding and payment amount for the T2Bacteria® Panel for FY 2020.

With regard to the newness criterion for the T2Bacteria ® Panel, we consider the beginning of the newness period to commence when the T2Bacteria ® Panel was cleared by FDA (May 24, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the T2Bacteria ® Panel onto the U.S. market (May 24, 2021) will occur in the second half of FY 2021, we proposed to continue new technology add-on payments for this technology for FY 2021. We proposed that the maximum new technology add-on payment for a case involving the T2Bacteria ® Panel would remain at $97.50 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for the T2Bacteria ® Panel). Cases involving the use of the T2Bacteria ® Panel that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XXE5XM5 (Measurement of infection, whole blood nucleic acid-base microbial detection, new technology group 5). We invited public comments on our proposal to continue new technology add-on payments for the T2Bacteria ® Panel for FY 2021.

Comment: Several commenters expressed support for our proposed continuation of new technology add-on payments for the T2Bacteria ® Panel for FY 2021. One commenter, who was also the applicant, stated that continuation of these payments for a second year is not only consistent with CMS' longstanding definition of newness but is also critical to increasing beneficiary access to the T2Bacteria ® Panel. The commenter noted that sepsis is the most expensive U.S. hospital-treated condition, representing $23.7 billion in healthcare costs per year and contributing to greater than 35% of inpatient deaths, many of them Medicare beneficiaries. The commenter concluded that, by enabling greater clinician access to the T2Bacteria ® Panel, CMS is playing a significant role in making sure Medicare beneficiaries receive the most effective therapy for the pathogen that they are infected with, reducing length-of-stay in the hospital and saving lives.

Response: We appreciate the commenters' support. After consideration of the public comments we received, we are finalizing our proposal to continue new technology add-on payments for the T2Bacteria ® Panel for FY 2021. The maximum new technology add-on payment amount for a case involving the T2Bacteria ® Panel will remain at $97.50 for FY 2021; that is, 65 percent of the average cost of the technology.

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Summary Table of FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments (NTAP)					
Technology	Newness Start Date	Continue or Discontinue NTAP for FY 2021	Previous Final Rule Citations	Maximum NTAP Amount for FY 2021	Coding Used to Identify Cases Eligible for NTAP
KYMRIAH® and YESCARTA®	November 22, 2017	Discontinue	(83 FR 41283 through 41299) and (84 FR 42185 through 42187)	None	XW033C3 or XW043C3
VYXEOS™	August 3, 2017	Discontinue	(83 FR 41299 through 41305) and (84 FR 42187 through 42188)	None	XW033B3 or XW043B3
VABOMERE™	August 29, 2017	Discontinue	(83 FR 41305 through 41311) and (84 FR 42188 through 42189)	None	XW033N5 or XW043N5 or National Drug Codes (NDC) 65293–0009–01 or 70842– 0120–01
remedē® System	October 6, 2017	Discontinue	(83 FR 41311 through 41320) and (84 FR 42189 through 42190)	None	0JH60DZ and 05H03MZ in combination with 05H33MZ or 05H43MZ
ZEMDRI™	June 25, 2018	Continue	(83 FR 41326 through 41334) and (84 FR 42190 through 42191)	$4,083.75	XW033G4 or XW043G4
GIAPREZA™	December 21, 2017	Discontinue	(83 FR 41334 through 41342) and (84 FR 42191)	None	XW033H4 or XW043H4
Sentinel® Cerebral Protection System	June 1, 2017	Discontinue	(83 FR 41342 through 41348) and (84 FR 42191 through 42192)	None	X2A5312
AQUABEAM System	December 21, 2017	Discontinue	(83 FR 41348 through 41355) and (84 FR 42192 through 42193)	None	XV508A4
AndexXa™	May 3, 2018	Continue	(83 FR 41355 through 41362) and (84 FR 42193 through 42194)	$18,281.25	XW03372 or XW04372
AZEDRA®	July 30, 2018	Continue	(84 FR 42194 through 42201)	$98,150	XW033S5 and XW043S5
CABLIVI®	February 6, 2019	Continue	(84 FR 42201 through 42208)	$33,215	XW013W5, XW033W5 and XW043W5
ELZONRIS™	December 21, 2018	Continue	(84 FR 42231 through 42237)	$125,448.05	XW033Q5 and XW043Q5
Balversa™	April 12, 2019	Continue	(84 FR 42237 through 42242)	$3,563.23	XW0DXL5
ERLEADA™	February 14, 2018	Discontinue	(84 FR 42242 through 42247)	None	XW0DXJ5
SPRAVATO™	March 5, 2019	Continue	(84 FR 42247 through 42256)	$1,014.79	XW097M5
XOSPATA®	November 28, 2018	Continue	(84 FR 42256 through 42260)	$7,312.50	XW0DXV5
JAKAFI™	May 24, 2019	Continue	(84 FR 42265 through 42273)	$4,096.21	XW0DXT5
T2Bacteria® Panel	May 24, 2018	Continue	(84 FR 42278 through 42288)	$97.50	XXE5XM5

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5. FY 2021 Applications for New Technology Add-On Payments (Traditional Pathway)

We received 17 applications for new technology add-on payments for FY 2021. In accordance with the regulations under § 412.87(e), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Two applicants withdrew their applications prior to the issuance of the proposed rule. Three applicants, Accelerate Diagnostics, Inc (the applicant for Accelerate PhenoTest™ BC kit), Kite Pharma (the applicant for KTE–X19) and Juno Therapeutics, a Bristol-Myers Squibb Company (the applicant for Liso-cel) did not meet the deadline of July 1 for FDA approval or clearance of the technology and, therefore, the technologies are not eligible for consideration for new technology add-on payments for FY 2021. We note that we did receive some comments requesting that CMS extend the July 1 deadline for applications to receive FDA marketing authorization for FY 2021 due to the COVID–19 public health emergency. The July 1 deadline for FDA approval or clearance for consideration of new technology add-on payment applications, as set forth in the regulations at § 412.87(e), continues to apply to applications for new technology add-on payments for FY 2021, subject to our proposed conditional approval process for certain antimicrobial products. A discussion of the remaining 12 applications, which met this deadline, is presented in this final rule.

b. BioFire ® FilmArray ® Pneumonia Panel

BioFire Diagnostics, LLC submitted an application for new technology add-on payments for the BioFire ® FilmArray ® Pneumonia Panel for FY 2021. According to the applicant, the BioFire ® FilmArray ® Pneumonia Panel identifies 33 clinically relevant targets, including bacterial and viral targets, from sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples in about an hour. The applicant also stated that for 15 bacteria, the BioFire ® FilmArray ® Pneumonia Panel provides semi-quantitative results, which may help determine whether an organism is a colonizer or a pathogen.

According to the applicant, lower respiratory tract infections are a leading cause of morbidity and mortality. The applicant stated that world-wide, they are the leading cause of infectious disease death and the 5th leading overall cause of death.[2] The applicant also asserted that in the United States, community acquired pneumonia (CAP) is the second most common cause of hospitalization and the most common infectious disease cause of death.[3] [4] The applicant also stated that in addition to CAP, Hospital-acquired Pneumonia (HAP) and Ventilator-associated Pneumonia (VAP) are the most common hospital acquired infections (HAI) accounting for 22 percent of all HAIs.[5] According to the applicant, HAP and VAP are of particular concern for patients admitted to intensive care units (ICUs) where mortality rates can be up to 50 percent.[6] [7]

According to the applicant, timely administration of effective antibiotics is essential for ensuring a good prognosis. The applicant stated that mortality increases for each hour of delay in initiating antibiotic therapy for hospitalized pneumonia patients,[8] [9] and ideally, antimicrobial therapy would be pathogen-specific and guided by the results of microbiology tests. However, the applicant stated that current microbiologic methods are slow and fail to identify a causative pathogen in over 50 percent of patients, even when comprehensive methods are used.[10] As a result, the applicant noted that current guidelines recommend empiric treatment with broad spectrum antibiotics,[11] and that broad-spectrum antibiotics lead to overuse of antibiotics, which increases the risk of an antibiotic related adverse event (for example, diarrhea, allergic reactions, C. difficile infection) for the patient and contributes to the well-known problem of antimicrobial resistance. In addition, the applicant noted that 6–15 percent of hospitalized patients with CAP fail to respond to the initial antibiotic treatment, in part due to ineffective antibiotic therapy.[12] [13] [14] [15]

According to the applicant, there are three current methods for determining the causative organism of pneumonia: bacterial culture, lab developed and commercial singleplex PCR (polymerase chain reaction) tests, and off-label use of upper respiratory multiplex syndromic panels.

According to the applicant, semi-quantitative bacterial culture is routinely performed on lower respiratory specimens. The applicant explained that a calibrated loop is used to spread sample on appropriate media. A quadrant streak method is generally employed and, depending on how many of the quadrants the organism grows in, determines its semi-quantification.

[2] Troeger, C., Forouzanfar, M., Rao, P.C., Khalil, I., Brown, A., Swartz, S., Fullman, N., Mosser, J., Thompson, R.L., Reiner Jr, R.C. and Abajobir, A., ''Estimates of the global, regional, and national morbidity, mortality, and aetiologies of lower respiratory tract infections in 195 countries: A systematic analysis for the Global Burden of Disease Study 2015,'' *The Lancet Infectious Diseases,* 2017, vol. 17(11), pp.1133–1161.

[3] Xu, J. Murphy SL, Kochanek KD, Bastian BA, ''Deaths: Final Data for 2013'' *Natl Vital Stat Rep,* 2016, vol. 64(2), p. 1.

[4] Pfuntner, A., Wier, L. M., & Stocks, C. ''Most frequent conditions in US hospitals, 2011,'' Healthcare Cost and Utilization Project (HCUP) Statistical Brief #162, 2013.

[5] Magill,.S., Edwards, J.R., Bamberg, W., Beldavs, Z.G., Dumyati, G., Kainer, M.A., Lynfield, R., Maloney, M., McAllister-Hollod, L., Nadle, J. and Ray, S.M., ''Multistate point-prevalence survey of health care–associated infections,'' *N. Engl. J. of Med.,* 2014, vol. 370(13), pp.1198–1208.

[6] Sopena, N., Sabrià, M. and Neunos 2000 Study Group, ''Multicenter study of hospital-acquired pneumonia in non-ICU patients,'' *Chest,* 2005, vol. 127(1), pp. 213–219.

[7] Esperatti, M., Ferrer, M., Giunta, V., Ranzani, O.T., Saucedo, L.M., Bassi, G.L., Blasi, F., Rello, J., Niederman, M.S. and Torres, A., ''Validation of predictors of adverse outcomes in hospital-acquired pneumonia in the ICU,'' *Crit. Care Med.,* 2013. Vol. 41(9), pp.2151–2161.

[8] Benenson, R., Magalski, A., Cavanaugh, S. and Williams, E., ''Effects of a pneumonia clinical pathway on time to antibiotic treatment, length of stay, and mortality,'' *Acad. Emerg. Med.,* 1999, vol. 6(12), pp.1243–1248.

[9] Houck, P.M., Bratzler, D.W., Nsa, W., Ma, A. and Bartlett, J.G., ''Timing of antibiotic administration and outcomes for Medicare patients hospitalized with community-acquired pneumonia,'' *Arch. Intern. Med.,* 2004, vol. 164(6), pp.637–644.

[10] Jain, S., Self, W.H., Wunderink, R.G., Fakhran, S., Balk, R., Bramley, A.M., Reed, C., Grijalva, C.G., Anderson, E.J., Courtney, D.M. and Chappell, J.D., ''Community-acquired pneumonia requiring hospitalization among US adults,'' *N. Engl. J. Med.,* 2015, vol. 373(5), pp.415–427.

[11] Kalil, A.C., Metersky, M.L., Klompas, M., Muscedere, J., Sweeney, D.A., Palmer, L.B., Napolitano, L.M., O'Grady, N.P., Bartlett, J.G., Carratalà, J. and El Solh, A.A., ''Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society,'' *Clin. Infect. Dis.,* 2016, vol. 63(5), pp.e61-e111.

[12] Rosón, B., Carratala, J., Fernández-Sabé, N., Tubau, F., Manresa, F. and Gudiol, F., ''Causes and factors associated with early failure in hospitalized patients with community-acquired pneumonia,'' *Arch. Intern. Med.,* 2004, vol. 164(5), pp.502–508.

[13] Menendez, R., Torres, A., Zalacain, R., Aspa, J., Villasclaras, J.M., Borderías, L., Moya, J.B., Ruiz-Manzano, J., de Castro, FR, Blanquer, J. and Pérez, D., ''Risk factors of treatment failure in community acquired pneumonia: Implications for disease outcome,'' *Thorax,* 2004. Vol. 59(11), pp. 960–965.

[14] Arancibia, F., Ewig, S., Martinez, J.A., Ruiz, M., Bauer, T., Marcos, M.A., Mensa, J. and Torres, A., ''Antimicrobial treatment failures in patients with community-acquired pneumonia: Causes and prognostic implications,'' *Am. J. Respir. Crit. Care Med.,* 2000, vol. 162(1), pp.154–160.

[15] Menéndez, R., Torres, A., Rodríguez de Castro, F., Zalacaín, R., Aspa, J., Martín Villasclaras, J.J., Borderías, L., Benítez, J.M.M., Ruiz-Manzano, J., Blanquer, J. and Pérez, D., ''Reaching stability in community-acquired pneumonia: The effects of the severity of disease, treatment, and the characteristics of patients,'' *Clin. Infect. Dis.,* 2004, vol. 39(12), pp.1783–1790.

According to the applicant, normal flora will often grow in all 4 quadrants and technicians must differentiate between potential pathogens and normal flora, and potential pathogens are picked from the plate and isolated on another media plate. According to the applicant, after growing isolate, final identification and susceptibility is performed.

According to the applicant, there are also FDA and lab-developed tests for single targets that cause pneumonia. The applicant stated that these are for the more serious pathogens (for example, Methicillin resistant *Staphylococcus aureus,* MRSA) or fastidious organisms (for example, *Mycobacterium tuberculosis*). According to the applicant, these tests range from sample-to-answer (Cepheid ® Xpert ® MTB/RIF) to lab-developed tests that are often multi-step and multiple pieces of equipment that require isolating nucleic acid from a sample and then adding appropriate reagents to perform a PCR assay on the isolated nucleic acid.

According to the applicant, a number of academic hospital labs have also performed off-label validation of commercially available respiratory panels designed for upper respiratory syndromes. The applicant stated that these tests are used primarily on BAL specimens for the rapid detection of viral causes of Pneumonia.

With respect to the newness criterion, the BioFire® FilmArray® Pneumonia Panel received FDA clearance via 510(k) on November 9, 2018, based on a determination of substantial equivalence to a legally marketed predicate device (Curetis Unyvero™). According to the applicant, the Pneumonia Panel was launched globally on December 11, 2018. According to the applicant, there was a delay between FDA clearance date and U.S. market availability (global launch date) in order to satisfy documentation requirements in preparation of the global launch. The applicant stated that it has been granted a Proprietary Laboratory Analyses (PLA) code by the American Medical Association; PLA Code 0151U was published on October 1, 2019 and became effective on January 1, 2020. According to the applicant, the PLA code assigned to the BioFire® FilmArray® Pneumonia Panel uniquely identifies this test and no other technologies use this code. The applicant submitted a request for approval for a unique ICD–10–PCS code for the administration of the BioFire® FilmArray® Pneumonia Panel beginning in FY 2021 and was granted approval for the following procedure code effective October 1, 2020: XXEBXQ6 (Measurement of infection, lower respiratory fluid nucleic acid-base microbial detection, new technology group 6).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the BioFire® FilmArray® Pneumonia Panel is the only sample-to-answer, rapid (~1 hour), and comprehensive molecular panel available for the diagnosis of the major bacterial and viral causes of infectious pneumonia. The applicant further explained that the BioFire® FilmArray® Pneumonia Panel is also the only semi-quantitative molecular solution available for rapidly diagnosing infectious causes of pneumonia. The applicant noted that this important feature allows labs and clinicians to better differentiate whether an organism is normal flora or the cause of the patient's illness. The applicant asserted that the current best practice is standard culture technique, discussed previously. The applicant further stated that other comprehensive molecular technologies include Curetis Unyvero™ which is a multi-step process, only has bacterial targets, and only provides qualitative results for all of its targets.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that potential cases representing patients who may be eligible for treatment involving the BioFire® FilmArray® Pneumonia Panel would be assigned to the same MS–DRGs as cases representing patients who receive diagnostic information from competing technologies.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the BioFire® FilmArray® Pneumonia Panel is the only FDA cleared comprehensive molecular panel approved for use on both sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples allowing for diagnosis of pneumonia in hospital, community, and ventilator associated populations. The applicant stated that the BioFire® FilmArray® Pneumonia Panel is also the only molecular panel that detects both bacterial and viral causes of lower respiratory infections and pneumonia.

In addition, the applicant added that the ability of the BioFire® FilmArray® Pneumonia Panel to detect pathogens and related susceptibility traits is a unique feature of the panel that differentiates it from existing respiratory panels that have been designed and approved for use on upper respiratory specimens and not lower respiratory specimens. The applicant stated that Furukawa, D., et al., evaluated the ability of the BioFire® FilmArray® Pneumonia Panel to detect pathogens and related susceptibility traits, specifically looking at the impact of MRSA detection, and showed that the BioFire® FilmArray® Pneumonia panel has the potential to significantly expedite time to MRSA results allowing for rapid escalation or de-escalation of therapy.[16]

We stated in the proposed rule that based on the applicant's statements as presented previously, we are concerned there is insufficient information to determine whether the BioFire® FilmArray® Pneumonia Panel mechanism of action is different from existing products. In the FDA decision summary, the test is described as a multiplex nucleic acid test, or PCR accompanied by the applicant's software. However, it is unclear from the new technology add-on payment application how the mechanism of action is new or different from other products that utilize PCR. While the applicant described this test as the only sample-to-answer, rapid (~1 hour), and comprehensive molecular panel available for the diagnosis of the major causes of infectious pneumonia and as also semi-quantitative, and further described another comprehensive molecular product (Curetis Unyvero™) as having only bacterial targets and providing only qualitative results for all of its targets, we stated that we are uncertain how the underlying mechanism of action of the BioFire® FilmArray® Pneumonia Panel is different from existing PCR-based tests. Additionally, based on the information provided by the applicant, we stated that it appears as though the product does not treat a different disease or population compared to other products. Finally, with respect to the Furukawa study, which the applicant cited to support that the BioFire has the potential to specifically expedite time to MRSA results allowing for rapid escalation or de-escalation of therapy,

[16] Furukawa, D., Kim, B., Jeng, A., BioFire® FilmArray® Pneumonia Panel: A Powerful Rapid Diagnostic Test for Antimicrobial Stewardship. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

we noted that the study authors also concluded that the BioFire® FilmArray® Pneumonia Panel ''has good agreement with SOC for detection of bacteria and viruses'' and that the BioFire® FilmArray® Pneumonia Panel ''detects additional *S. aureus* bacteria not reported by SOC,'' but that ''[a]dditional *S. aureus* detection are more likely to be at low concentration and are of unclear clinical significance.'' We invited public comments on whether the BioFire® FilmArray® Pneumonia Panel is substantially similar to other technologies and whether the BioFire® FilmArray® Pneumonia Panel meets the newness criterion.

We did not receive any public comments on whether the BioFire® FilmArray® Pneumonia Panel meets the newness criterion. We continue to have the same concerns as summarized in the proposed rule that the BioFire® FilmArray® Pneumonia Panel is substantially similar to other products that are currently available on the U.S. market. Despite the information the applicant previously submitted with its application describing the BioFire® FilmArray® Pneumonia Panel as the only sample-to-answer, rapid (~1 hour), and comprehensive molecular panel available for the diagnosis of the major causes of infectious pneumonia and as also semi-quantitative, it remains unclear how the mechanism of action is specifically new or different from other products that utilize PCR. Moreover, it appears that the patient population of cases that may be eligible for tests using the BioFire® FilmArray® Pneumonia Panel also currently has access to other PCR-based tests and similar technologies that are also used in the testing of similar conditions. Therefore, we are unable to determine that the BioFire® FilmArray® Pneumonia Panel meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion.

The applicant stated that it used 2018 data from Definitive Health Care at *defhc.com*, and that it searched these data for cases in MS–DRGs 193, 194, and 195 (Simple Pneumonia and Pleurisy with MCC, with CC, and without CC/MCC, respectively), which resulted in 297,956 cases. The applicant indicated that the data was from proprietary data drawn from one hospital in Indianapolis in 2018. However, the scope of the data as described by the applicant is unclear to us, as it seems unlikely that a single hospital in Indiana would have observed 297, 956 cases of simple pneumonia in 1 year. It is also not clear how these cases correspond to any of the later steps in the cost analysis. For example, the applicant did not indicate whether the charge values from the data are based on the same 297,956 cases identified in the three MS–DRGs.

In its analysis, the applicant stated that no charges were removed for any prior technologies as the BioFire® FilmArray® Pneumonia Panel does not eliminate culture testing of specimens. The applicant standardized the charges and then inflated the charges. The applicant reported using an inflation factor of 5.50 percent based on the charge inflation factor published by CMS in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). The applicant appears to have made a minor error in this inflation factor, since the actual, 1-year inflation factor in the FY 2020 IPPS/LTCH PPS final rule was 5.4 percent. To estimate the cost of the technology, the applicant used the per-test list price cost of the BioFire® FilmArray® Pneumonia Panel. The applicant indicated that it did not incorporate an estimate of technician time spent administering the test, asserting that ''2–5 minutes of technician time is nearly obsolete due to ease of use of the test.'' The applicant also indicated that it did not incorporate an estimate of instrumentation cost into its costing of the BioFire® FilmArray® Pneumonia Panel, noting that ''a number of'' labs already have sufficient instrumentation to run the BioFire® FilmArray® Pneumonia Panel test. The applicant added charges for the BioFire® FilmArray® Pneumonia Panel based on an estimated range of projected patient charges for the BioFire® FilmArray® Pneumonia Panel technology. The applicant stated that the charge to the patient varies by location and the methodology of the hospital or lab charge master. The applicant noted that the estimate was based on patient charges for other BioFire® products that had been reported by hospitals and reference labs. Based on this analysis, the applicant computed a final inflated average case-weighted standardized charge per case of $78,156, as compared to an average case-weighted threshold amount of $42,812. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We stated in the proposed rule that we are concerned that many of the calculated values in the applicant's analysis, such as the average-cost-per case, unweighted and unstandardized, were reportedly based on proprietary claims data that came from one hospital in Indianapolis. We are concerned that an analysis based on one hospital would not adequately represent the cost of cases using the BioFire® FilmArray® Pneumonia Panel as the data could be skewed or biased based on one hospital. We stated in the proposed rule that we are also concerned with the lack of description of how the BioFire® FilmArray® Pneumonia Panel maps to the three MS–DRGs for simple pneumonia (that is, MS–DRGs 193, 194 and 195); for example, whether the analysis included all the cases in these MS–DRGs or was limited to specific cases. We note there are several additional pneumonia-related MS–DRGs to which we believe potential cases that may be eligible for the use of the product could be mapped, but which were not included in the cost analysis; for example, MS–DRGs 177, 178 and 179 (Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively). We invited public comments on whether the BioFire® FilmArray® Pneumonia Panel meets the cost criterion.

We did not receive any public comments on whether the BioFire® FilmArray® Pneumonia Panel meets the cost criterion. We continue to have the same concerns regarding the cost analysis for the BioFire® FilmArray® Pneumonia Panel as summarized previously. We remain concerned that many of the calculated values in the applicant's analysis would not adequately represent the cost of cases using the BioFire® FilmArray® Pneumonia Panel as they are based on proprietary claims data that came from one hospital. We also continue to be concerned with the lack of description of how the BioFire® FilmArray® Pneumonia Panel maps to the three MS–DRGs for simple pneumonia (that is, MS–DRGs 193, 194 and 195); for example, whether the analysis included all the cases in these MS–DRGs or was limited to specific cases. Therefore, we are unable to determine that the BioFire® FilmArray® Pneumonia Panel meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that data from studies conducted with the BioFire® FilmArray® Pneumonia Panel show that it can detect major causes of pneumonia with a high degree of sensitivity and specificity in a clinically relevant timeframe. The applicant explained that results from the BioFire® FilmArray®

Pneumonia Panel also have the potential to impact antibiotic usage and lead to improved stewardship and possible cost savings.

The applicant submitted four studies presented as posters at national conferences to support its assertion that the product represents a substantial clinical improvement, noting that data for this test is still new and has not yet been published in academic journals.

According to the applicant, Buchan, et al. compared the results of conventional testing (bacterial culture and clinician directed molecular testing for viruses and atypical bacteria) with the results from the BioFire® FilmArray® Pneumonia Panel for 259 BAL and 48 sputum samples.[17] We note that in their poster, Buchan, et al. specified that conventional testing specifically included bacterial culture and PCR based on clinician order. Also, while Buchan, et al. did report on the BAL specimens, the poster did not appear to report information regarding sputum samples. According to Buchan, et al., specimens were obtained from inpatients aged 18 years and older with symptoms of respiratory tract infection at 8 hospitals in the U.S. Chart review was conducted to determine type and duration of antibiotic therapy for each subject. According to the applicant, at least one bacterial pathogen was identified by standard methods and by the BioFire® FilmArray® Pneumonia Panel for 23 percent of BALs samples (n=60) and 35 percent (n=17) of sputum samples; however, the BioFire® FilmArray® Pneumonia Panel detected a bacterial pathogen in an additional 15 percent (n=40) of BAL samples and 21 percent (n=10) of the sputum samples. For the 259 BAL samples, 75 bacteria were identified by both standard methods and by the BioFire® FilmArray® Pneumonia Panel. The applicant noted that the BioFire® FilmArray® Pneumonia Panel identified an additional 84 bacteria, with the most common detections for *Staphylococcus aureus* (N=21), *Haemophilus influenzea* (n=19), *Moxaella catarrhalis* (n=8), *Pseudomonas aeruginosa* (n=6) and *Klebsiella oxytoca* (n=6). The applicant also explained that an evaluation of the medical and laboratory records for the affected patients found that 50 percent had been on antibiotics within 72 hours of samples collection, 42 percent of the organisms may have been present in the culture but were not reported (due either to low quantification ($<10^4$ cfu/mL) or the presence of mixed colonies) and only 8 percent of the detections were unexplained.

According to the applicant, an important feature of the BioFire® FilmArray® Pneumonia Panel is the inclusion of assays for viral agents. The applicant noted that in Buchan, et al., the BioFire® FilmArray® Pneumonia Panel identified at least 1 virus in 19 percent of 259 BAL samples from hospitalized adults[18] and viruses were the only pathogen detection in 12 percent (n=31) of BAL specimens, while 7 percent (n=18) had both bacterial and viral pathogen detections. The applicant summarized that the most common viral pathogens were human rhinovirus (n=17), coronavirus (n=9) and influenza (n=5). Twenty-three percent of the samples with a viral detection had a corresponding test ordered as part of standard of care. The applicant stated that this finding highlights that the role of viruses in pneumonia is still under appreciated. The applicant further stated that identification of a viral agent in the absence of a bacterial detection may allow reduction in the use of antibiotics.

According to the applicant, the ability of the BioFire® FilmArray® Pneumonia Panel to impact patient management has been evaluated by two different groups (Buchan, et al. and Enne, et al). The applicant stated that Buchan, et al. performed a theoretical outcomes analysis by using the result of the BioFire® FilmArray® Pneumonia Panel to modify antimicrobial therapy and then judge if the modification was correct using the final microbiology results. The applicant explained that in this analysis of 243 BAL samples, 68 percent (n=165) could have had an antibiotic adjustment; 48 percent (n=122) would have had antibiotics appropriately de-escalated or discontinued, 31 percent (n=78) would have had no change, and 2 percent (n=5) would have had appropriate escalation or initiation of antibiotics.[19] Alternately, 17 percent (n=42) would have received inappropriate escalation and 2 percent (n=6) would have received inappropriate de-escalation when compared to culture results. The applicant summarized that the most common de-escalations occurred due to discontinuation of vancomycin due to non-detection of MRSA (35 percent) and discontinuation of piperacillin/tazobactam due to non-detection of *Enterobacteriaceae* (23 percent). According to the applicant, the de-escalation due to non-detection of these pathogens is possible because the increased sensitivity of the BioFire® FilmArray® Pneumonia Panel for detection of bacterial pathogen provides a high negative predictive value for these non-detections. The applicant explained that the authors estimated the results could have potentially saved >18,000 antibiotic hours equating to an average of 6.5 days/patient (we note that in the poster by Buchan, et al., they reported an average of 6.2 d/patient rather than 6.5 mentioned in the application).[20]

According to the applicant, in an analysis of 120 ICU patients (79 males and 41 females; 33 children, with a median age of 1; and adults with a median age of 68) in the UK by Enne, et al., patients were divided into a group with positive outcomes (pneumonia resolved within 21 days) and negative outcomes (pneumonia not resolved in 21 days or contributed to the patient's death). Enne, et al., evaluated the appropriateness of antimicrobials used for HAP/VAP versus both routine culture and two rapid PCR tests, BioFire® FilmArray® Pneumonia Panel (1h) and Curetis Unyvero™ Pneumonia Panel (5.5h). Consented or assented ICU patients were recruited at 4 diverse UK hospitals: 1 district general, 1 tertiary referral, 1 children's and 1 private. Patients were those starting or changing antibiotics for suspected pneumonia, already hospitalized for >48h and with a timely respiratory sample. According to the applicant, the results of the BioFire® FilmArray® Pneumonia Panel and routine culture were evaluated to determine if the test results would have identified the antibiotic therapy as active or inactive. The applicant explained that in the group with positive outcomes, the results of the BioFire® FilmArray® Pneumonia Panel were able to correctly classify the patient's therapy as active for 35 percent of patients compared to only 20 percent for routine culture (p=0.005). The applicant also explained that in the group of 27 percent of patients that had negative outcomes, the results of the BioFire® FilmArray® Pneumonia Panel would have classified the initial antibiotic therapy as inactive for 41 percent of patients compared to only 15.6 percent for routine culture.[21] The

[17] Buchan, B.W., Windham, S., Faron, M.L., et al. Clinical Evaluation and Potential Impact of a Semi-Quantitative Multiplex Molecular Assay for the Identification of Pathogenic Bacteria and Viruses in Lower Respiratory Specimens. Poster presented at American Thoracic Society; 2018 May 02. San Diego, CA.

[18] Ibid.

[19] Ibid.

[20] Ibid.

[21] Enne, V.I., Baldan, R., Russell, C., et al. INHALE WP2: Appropriateness of Antimicrobial Prescribing for Hospital-acquired and Ventilator-associated Pneumonia (HAP/VAP) in UK ICUs assessed against PCR-based Molecular Diagnostic Tests. Poster presented at European Congress of

Continued

study authors also reported that routine microbiology and Curetis Unyvero™ detected a potential pathogen in 41.7 percent and 59.2 percent of specimens respectively, whereas BioFire® FilmArray® Pneumonia Panel detected a potential pathogen in 66.7 percent of respiratory samples from patients enrolled in the study. The applicant stated that these study results indicate that the test results of the BioFire® FilmArray® Pneumonia Panel provide information that can lead to more targeted and effective therapy in a shorter period of time, and may help to improve patient outcomes.

The applicant also submitted Rand et al., which conducted a retrospective analysis of BAL (n=197) and endotracheal aspirates (n=93) samples from 270 unique hospitalized patients that were collected and stored at −70° C until thawed and tested on the BioFire® FilmArray® Pneumonia Panel compared to routine microbiology results.[22] Patient data were extracted from the electronic medical record. Cultures were performed by standard methods and identified by Vitek II and mass spectrometry. The applicant explained that the authors found a high correlation between standard methods and BioFire® FilmArray® results and that the authors concluded the BioFire® FilmArray® Pneumonia Panel would have had a significant impact on time to result which could potentially lead to more rapid and appropriate use of antibiotics. The applicant also noted that the authors found significant association with clinical/outcome variables and that the BioFire® FilmArray® Pneumonia Panel's semi-quantification was ''at least as strong'' as standard culture methods, which according to the applicant, have been developed and improved over decades.

The applicant also submitted White, et al., which conducted a comparison of the BioFire® FilmArray® Pneumonia Panel on sputum samples to a multi-test diagnostic bundle for patients admitted from the emergency department (ED) with community acquired pneumonia (CAP).[23] We note that White, et al. specifically described the diagnostic bundle as including the following: (1) Blood Cultures; (2) Sputum culture and sensitivity; (3) Urine antigens: *Legionella and S. pneumoniae;* (4) Nasal swab (NS) PCR for *MRSA* and *S. pneumoniae;* (5) FilmArray (Biofire) PCR Panel (NS): Detects 17 viruses, 4 bacteria. Of 585 enrolled patients, 278 were evaluable. The applicant explained that the authors found that the BioFire® FilmArray® Pneumonia Panel detected a higher rate of potential pathogens than the multi-test bundle (90.6 percent versus 81 percent). The applicant also noted that the authors determined that the urine antigen testing, *S. aureus* and *S. pnuemoniae,* and PCR upper respiratory panel use could be eliminated for this sample/patient type in the future.[24]

The applicant also submitted a poster by Furukawa, et al. which reported a retrospective case review of 43 samples (17 used for clinical use and 26 obtained randomly by microbiology lab) in which BioFire® FilmArray® Multiplex PCR was utilized.[25] According to the applicant, initial use of BioFire FilmArray Pneumonia panel had 100 percent intervention rate leading to de-escalation or prevention of inappropriate antibiotics and the authors found that there was a low risk of unnecessary antibiotics being administered due to the increased sensitivity of the BioFire® FilmArray® Pneumonia panel. The applicant added that the authors believe that with additional data they may be able to discontinue empiric broad spectrum coverage due to the rapid and sensitive nature of the BioFire FilmArray Pneumonia Panel. The applicant also noted that they have a number of ongoing prospective studies being conducted to further support their claims.

The applicant asserted that Buchan, et al. and Rand, et al. support their claim of decreased time to actionable results based on: (1) The conclusion in Buchan, et al., that greater than 60 percent of patients potentially could have had an antibiotic adjustment 3–4 days earlier than standard methods based on BioFire® FilmArray® Pneumonia Panel results, and (2) the conclusion in Rand, et al., that the BioFire® FilmArray® Pneumonia Panel would have a major impact on the time to report potential pathogens that may cause Pneumonia in intubated/ICU patients.

The applicant asserted that Buchan, et al., and Enne, et al. support their claim of improved antibiotic stewardship. The applicant pointed to the conclusions in Buchan, et al., that >60 percent of patients potentially could have had an antibiotic adjustment with BioFire® FilmArray® Pneumonia Panel results and 50 percent of potential antibiotic adjustments from BioFire® FilmArray® Pneumonia Panel testing were discontinuation or narrowing, as well as the estimate that the BioFire® FilmArray® Pneumonia Panel results enabled >18,000 antibiotic hours saved on 243 patients. The applicant pointed to Enne, et al. for the results that of the 27 percent of patients who had negative outcomes, 15.6 percent had a pathogen resistant to initial therapy based on culture and 41.9 percent were resistant to initial therapy based on BioFire® FilmArray® Pneumonia Panel results (p=0.029).

The applicant asserted that White, et al. and Enne, et al. support its claim of increased diagnostic yield because White, et al. concluded that of patients with a final diagnosis of pneumonia, BioFire® FilmArray® Pneumonia Panel detected a potential pathogen in 90.6 percent compared to 81 percent with standard methods, and Enne, et al. reported that routine methods detected a pathogen in 41.7 percent of specimens compared to the BioFire® FilmArray® Pneumonia Panel which detected a pathogen in 66.7 percent of specimens.

In summary, the applicant explained that lower respiratory tract infections are a common and serious health care problem, current diagnostic tests are slow and do not identify a causative pathogen in over 50 percent of patients, and the BioFire® FilmArray® Pneumonia Panel is an easy-to-use multiplex panel that has been shown to increase diagnostic yield and significantly decrease time to results when compared to standard testing both because of improved test sensitivity and because it includes assays for typical bacteria, viruses and selected antibiotic resistance genes. According to the applicant, retrospective review of BioFire® FilmArray® Pneumonia Panel and patient data indicates a potential to impact antibiotic utilization to ensure patients are on appropriate therapy in a timely manner. The applicant also noted that molecular testing for pneumonia is relatively new and there is a lot to learn about how to best use these tests, and that there are currently several prospective studies underway to clarify the role that this tool may play in improving the outcomes for patients with pneumonia, reducing use of unnecessary antibiotics, improving targeted therapy and potentially reducing health care costs due to more directed and efficient patient

Clinical Microbiology and Infectious Disease; 2019 April 13–16. Amsterdam, Netherlands

[22] Rand, K.H., Beal S.G., Cherabuddi, K., et al. Relationship of a Multiplex Molecular Pneumonia Panel (PP) Results with Hospital Outcomes and Clinical Variables. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

[23] White, E., Ferdosian, S., Gelfer, G., et al. Sputum FilmArray Pneumonia Panel Outperforms A Diagnostic Bundle in Hospitalized CAP Patients. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC

[24] Ibid.

[25] Furukawa, D., Kim, B., Jeng, A., BioFire® FilmArray® Pneumonia Panel: A Powerful Rapid Diagnostic Test for Antimicrobial Stewardship. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

management. According to the applicant, early theoretical outcomes evaluations provide reason to be optimistic.

We noted in the proposed rule that the studies the applicant submitted to support its assertions regarding substantial clinical improvement were presented only as posters, and that information pertaining to full manuscripts with further study details were not provided. We stated that it is also unclear if the studies described in the posters have been submitted for peer-reviewed publication or whether full manuscripts with detailed methods and data tables are available.

We stated in the proposed rule that we are concerned that the studies do not appear to be designed or powered to be able to show conclusive evidence of clinical impact. In particular, the studies appear to describe analysis of clinical results for patients and state that there is potential for the results to impact clinical decisions about antimicrobial therapy. However, it appears the applicant did not submit evidence of the BioFire® FilmArray® Pneumonia Panel product in real-world, prospective use (randomized or non-randomized) with actual antimicrobial decisions or effect on patient management. This may require larger sample sizes. We stated that we are also concerned that only one study provided by the applicant (Enne, et al.) compared BioFire® FilmArray® Pneumonia Panel to Curetis Unyvero™, which is another PCR-based technology, and that a statistical difference was not reported between BioFire and Unyvero for the outcomes reported in the poster. While we understand that Curetis Unyvero™ may be somewhat slower than BioFire® FilmArray® Pneumonia Panel and does not include viruses, the clinical impact of the differences between these two products is unclear. We stated that we are also uncertain how Buchan, et al. calculated their estimate that >18,000 antibiotic hours were saved on 243 patients using the BioFire® FilmArray® Pneumonia Panel results. The applicant stated that there are currently several prospective studies underway to clarify the role that this tool may play in improving the outcomes for patients with pneumonia, reducing use of unnecessary antibiotics, improving targeted therapy and potentially reducing health care costs due to more directed and efficient patient management; however, data or results from those studies were not included with the application. We invited public comment on whether the BioFire® FilmArray® Pneumonia Panel meets the substantial clinical improvement criterion.

Comment: One commenter suggested that the BioFire® FilmArray® Pneumonia Panel, as well as other rapid infectious diseases diagnostics tests, be evaluated based on their clinical improvements over historical microbiology testing methods as opposed to other rapid tests currently in the marketplace.

Response: We appreciate the commenter's input and suggestion. We note that consistent with our current approach in evaluating the new technology add-on payment substantial clinical improvement criterion we accept a wide range of data and other evidence to support the conclusion of substantial clinical improvement, including data regarding historical technologies and currently available technologies. We refer the commenter to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42289 through 42292) for further discussion of the substantial clinical improvement criterion as well as to the regulations at § 412.87(b). For the purposes of evaluating whether the BioFire® FilmArray® Pneumonia Panel meets the substantial clinical improvement criterion, data regarding both historical technologies and currently available technologies were considered.

We did not receive any public comments addressing the concerns we indicated in the proposed rule regarding whether the BioFire® FilmArray® Pneumonia Panel meets the substantial clinical improvement criterion. Accordingly, after consideration of the public comment we received, we are unable to determine that the BioFire® FilmArray® Pneumonia Panel represents a substantial clinical improvement over the currently available technologies.

After consideration of the information previously submitted in the BioFire® FilmArray® Pneumonia Panel application and previously summarized in this final rule, and the public comment we received, we are unable to determine that the BioFire® FilmArray® Pneumonia Panel meets the newness, cost and substantial clinical improvement criteria. Therefore, we are not approving new technology add-on payments for the BioFire® FilmArray® Pneumonia Panel for FY 2021.

c. ContaCT

Viz.ai Inc. submitted an application for new technology add-on payments for ContaCT for FY 2021. The individual components of ContaCT are currently marketed by Viz.ai, Inc. under the tradenames ''Viz LVO'' (for the algorithm), ''Viz Hub'' (for the text messaging and calling platform), and ''Viz View'' (for the mobile image viewer). According to the applicant, ContaCT is a radiological computer-assisted triage and notification software system intended for use by hospital networks and trained clinicians. The applicant asserted that ContaCT analyzes computed tomography angiogram (CTA) images of the brain acquired in the acute setting, sends notifications to a neurovascular specialist(s) that a suspected large vessel occlusion (LVO) has been identified, and recommends review of those images.

The applicant asserted early notification of the stroke team can reduce time to treatment and increase access to effective specialist treatments, like mechanical thrombectomy. Specifically, the applicant asserted that shortening the time to identification of LVO is critical because the efficacy of thrombectomy in patients with acute ischemic stroke decreases as the time from symptom onset to treatment increases. The applicant also asserted in a condition like stroke, where 1.9 million neurons die every minute and for which 34 percent of patients hospitalized are under the age of 65, reducing time to treatment results in reduced disability.[26] The applicant asserted ContaCT streamlines the standard workflow using artificial intelligence to substantially shorten the period of time between when a patient receives a stroke CT/CTA and when the patient is referred to a stroke neurologist and neurointerventional surgeon.

With respect to the newness criterion, according to the applicant, FDA granted marketing authorization to ContaCT on February 13, 2018 under the *de novo* pathway, which is only available to devices of a new type with low-to-moderate risk for which there are no legally marketed predicates, and classified it as a Class II medical device. We note that FDA issued a *de novo* order memorandum describing ContaCT as ''an artificial intelligence algorithm [used] to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation.'' The order specified that ''identification of suspected findings is not for diagnostic use beyond notification.''

[26] Hall MJ, Levant S, DeFrances CJ. Hospitalization for stroke in U.S. hospitals, 1989–2009. NCHS data brief, no 95. Hyattsville, MD: National Center for Health Statistics. 2012. *https://www.cdc.gov/nchs/data/databriefs/db95.pdf.*

The applicant asserted that ContaCT was not available immediately after FDA's marketing authorization due to establishing Quality Management Systems and processes for distributing ContaCT as well as staff training and installation. Per the applicant, ContaCT was not commercially available until October 2018. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the administration of ContaCT beginning in FY 2021 and was granted approval for the following procedure code effective October 1, 2020: 4A03X5D (Measurement of arterial flow, intracranial, external approach).

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted no existing technology is comparable to ContaCT. The applicant further asserted, because of the technology's novelty, the product was reviewed under FDA's *de novo* pathway. The applicant first outlined the clinical workflow for patients presenting to a hospital with signs or symptoms of LVO prior to the availability of ContaCT:

1—Patient presents with stroke/suspected stroke to hospital emergency department (ED).

2—Patient receives stroke CT/CTA imaging after brief initial evaluation by hospital ED physician.

3—Technologist processes and reconstructs the CT/CTA imaging and manually routes to hospital picture archiving and communication system (PACS).

4—Radiologist reads CT/CTA imaging.

5—If needed, a neuroradiology consult is sought.

6—A radiological diagnosis of LVO is made.

7—The radiologist informs hospital ED physician of positive LVO either verbally or in the radiologist report.

8—ED physician performs comprehensive exam and refers the patient to a stroke neurologist.

9—The stroke neurologist reviews the CT/CTA imaging and clinical history and determines whether to prescribe or recommend prescription of thrombolysis with tissue plasminogen activator (tPA).

10—The stroke neurologist refers the patient to a neurointerventional surgeon. Together they decide whether the patient is a candidate for mechanical thrombectomy.

11—If appropriate, the patient proceeds to treatment with mechanical thrombectomy.

The applicant asserted that facilities utilizing the ContaCT system can substantially shorten the period of time between when the patient receives stroke CT/CTA imaging (step 2) and when the patient is referred to a stroke neurologist and neurointerventional surgeon (steps 9 and 10). They further asserted that ContaCT streamlines this workflow using artificial intelligence to analyze CTA images of the brain automatically and notifies the stroke neurologist and neurointerventional surgeon that a suspected LVO has been identified, and then enables them to review imaging and make a treatment decision faster. The applicant concluded that shortening the time to identification of LVO is critical because the efficacy of thrombectomy in patients with acute ischemic stroke decreases as the time from symptom onset to treatment increases.

With regard to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant did not specifically address whether the technology meets this criterion. However, we believe that cases involving the use of the technology would be assigned to the same MS–DRGs as cases without the technology where the patient moves through the hospital according to the traditional workflow outlined above.

With regard to the third criterion, whether the use of the new technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant also did not specifically address whether the technology meets this criterion. However, we stated in the proposed rule that we believe cases involving the use of the technology would treat the same or similar type of disease and the same or similar patient population as the traditional workflow outlined above.

We noted that the applicant described ContaCT's mechanism of action as shortening the time to identification of LVO through artificial intelligence (AI). Specifically, the applicant asserted that facilities utilizing the ContaCT system can substantially shorten the period of time between when the patient receives stroke CT/CTA imaging and when the patient is referred to a stroke neurologist and neurointerventional surgeon. We stated in the proposed rule that we were unclear as to whether the streamlining of hospital workflow would represent a unique mechanism of action. Rather, we stated that it seems that the mechanism of action for ContaCT would be the use of AI to analyze images and notify physicians rather than streamlining hospital workflow. However, we also referred the reader to our discussion below and in the proposed rule regarding our concerns with respect to general parameters for identifying a unique mechanism of action based on the use of AI, an algorithm and/or software.

To the extent that the applicant asserted that streamlined hospital workflow through the use of ContaCT represents a unique mechanism of action, we stated in the proposed rule that it was unclear to us the degree to which ContaCT changes the traditional workflow. Per the FDA, ''ContaCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to confirm diagnosis.'' [27] We stated that it was unclear to CMS how ContaCT shortens time to treatment via AI if the CT machine still performs the scanning and clinicians are still needed to view the images to diagnose an LVO and perform a full patient evaluation for the best course of treatment. The applicant also indicated to CMS that the use of ContaCT is not automatic, and the E.R. physician must submit an order to utilize it specifically when suspecting an LVO. We stated that we were unclear how ContaCT streamlines the workflow for stroke treatment via AI if it is not to be used for diagnostic purposes per the FDA and still requires personnel to order the scan and make the diagnosis.

We stated in the proposed rule that we were also generally concerned as to whether the use of AI, an algorithm or software, which are not tangible, may be considered or used to identify a unique mechanism of action. In addition, we questioned how updates to AI, an algorithm or software would affect an already approved technology or a competing technology, including whether software changes for an already approved technology could be considered a new mechanism of action. We also questioned whether, if there were competing technologies to an already approved AI new technology, an improved algorithm by a competitor would represent a unique mechanism of action if the outcome is the same as the technology first approved. We welcomed comments from the public regarding the general parameters for identifying a unique mechanism of

[27] U.S. Food and Drug Administration, DEN170073. *Evaluation of Automatic Class III Designation for ContaCT Decision Summary.*

action based on the use of AI, an algorithm and/or software.

We also invited public comments on whether the applicant meets the newness criterion, including specifically with respect to the mechanism of action.

Comment: The applicant submitted a comment to address newness concerns raised by CMS in the proposed rule. The applicant asserted that there was a brief delay in the availability of ContaCT due to establishing Quality Management Systems (QMS) and processes for distributing ContaCT. Because of this delay, the first hospital installation of ContaCT was not completed until January 2019. According to the applicant, because the commercial use of ContaCT did not begin at the start of FY 2019, the Medicare data which is used to set FY 2021 MS–DRG relative weights (data from FY 2019 October 1, 2018 through September 30, 2019), do not reflect fully the cost of the technology. Therefore, the applicant believed that the newness period should begin on the date the first installation was completed, rather than the date of commercial availability noted in the FY 2019 IPPS/LTCH PPS proposed rule (85 FR 32601), which was October 2018.

The applicant asserted that no existing technology is comparable to ContaCT. According to the applicant, with regard to the first criterion for newness, ContaCT does not use the same or a similar mechanism of action as compared to an existing technology. The applicant stated that ContaCT was reviewed through FDA's *de novo* pathway, which is only available to novel medical devices that have not previously been classified by the FDA. With regard to the second criterion for newness, the applicant stated that ContaCT is used in cases of stroke and suspected stroke. Consequently, stroke and suspected stroke cases in which ContaCT is used are expected to be assigned to the same DRGs as stroke and suspected stroke cases without the technology. With regard to the third criterion for newness, the applicant stated that cases in which ContaCT is used are expected to be the same or similar to cases without the technology.

With respect to the first substantial similarity criterion, the applicant asserted that computer-assisted triage and notification is the mechanism of action for ContaCT and that the mechanism of action for ContaCT is not AI per se. According to the applicant, AI is a necessary component of ContaCT, but is not sufficient to achieve therapeutic effect. Furthermore, the applicant stated that under 42 CFR 412.87(b)(2) and CMS criteria for evaluating a technology with respect to newness, there are no requirements that a new technology have a specific type of mechanism of action to be eligible for new technology add-on payments.

The applicant expressed concern that CMS is questioning whether AI, an algorithm or software may never be considered a unique mechanism of action, because such technology may simulate human intelligence or human processes that already exist. According to the applicant, CMS has defined an existing technology as another FDA approved or cleared technology. Human intelligence and human processes are not FDA approved or cleared technologies and, therefore, should not be used as a comparator to evaluate whether ContaCT, or any technology, meets the definition of newness. The applicant stated that, as for other new technologies, comparators for AI, algorithm or software-based devices should be other FDA approved or cleared technologies. More broadly, the applicant urged CMS not to make a broad determination that technologies that use AI, an algorithm or software to achieve a therapeutic effect are ineligible for new technology add-on payments. They stated CMS should evaluate each new technology individually with respect to whether it meets the established criteria.

In addressing CMS concerns about whether software changes for an already approved technology could be considered a new mechanism of action, the applicant stated that an update to the ContaCT algorithm that does not alter this mechanism of action would have the same or a similar mechanism of action. In addressing CMS concerns about whether an improved algorithm by a competitor would represent a unique mechanism of action if the outcome is the same as the technology first approved, the applicant likewise stated that a different technology that shortens time to notification in patients with acute ischemic stroke caused by large vessel occlusions by using an AI algorithm to identify suspected LVO, triage patients and notify the stroke team more rapidly would likely be determined to have a mechanism of action that is the same or similar to ContaCT.

In addition, the applicant stated that the newness of the overall mechanism of action or the means by which a product achieves the therapeutic outcome should be assessed, rather than the newness of the individual inputs or components. They provided an example from FY 2017 when CMS determined MIRODERM not to be ''new'' because the product achieved the intended therapeutic outcome, wound healing, in the same way as other acellular skin substitutes by providing a scaffold of collagen with a mix of matrix proteins (81 FR 56893). The applicant stated that CMS acknowledged that MIRODERM matrix proteins were different from the proteins found in other acellular skin substitutes, but the determination of newness was based on MIRODERM's overall mechanism of action—a collagen scaffold that promotes wound healing. Just as in the MIRODERM example where the matrix proteins were not sufficient to establish the technology as new, changes to the AI, algorithm and/or software would not be sufficient to establish future computer-aided triage and notification systems for large vessel occlusion ischemic stroke as new if these involve essentially the same mechanism of action as ContaCT. The applicant thus argued that technologies that utilize AI, an algorithm and/or software should be evaluated for newness in the same way as CMS evaluates any other medical device applying for new technology add-on payments.

Other commenters responded to CMS' concerns about whether the applicant meets the newness criterion. In response to our stated uncertainty regarding how ContaCT streamlines the workflow for stroke treatment via AI if it is not to be used for diagnostic purposes per the FDA and still requires personnel to order the scan and make the diagnosis, a commenter responded that ContaCT will enhance, not replace, human action as it relates to patient outcomes, and asserted that all innovation will be based upon AI in some fashion moving forward. Another commenter responded to our concerns as to whether the use of AI, an algorithm or software may be considered or used to identify a unique mechanism of action and also how updates to AI, an algorithm or software would affect an already approved technology or a competing technology for purposes of new technology add-on payments. The commenter stated that technologies that utilize AI, an algorithm and/or software may be evaluated for newness in the same way CMS evaluates any other medical device applying for new technology add-on payments. Such a technology would not be new if there is an existing FDA-approved technology that has been on the market for more than 2 to 3 years and that has the same mechanism of action, is assigned to the same DRGs, or is used in the same or similar type of disease and patient population. The commenter further suggested that this apply to both incremental changes to

the same device as well as to competing devices. The commenter urged CMS to consider that evaluating technologies that use AI, an algorithm and/or software is no different than evaluating other technologies for purposes of new technology add-on payments. They stated that technologies are not required to have a specific type of mechanism of action to be eligible for add-on payment, and as such, each submission must be evaluated independently.

Response: After considering the comments received regarding the new technology add-on payment application for ContaCT, we agree that ContaCT does not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared to existing treatments because there are currently no FDA approved or cleared technologies that use computer-assisted triage and notification to rapidly detect an LVO and shorten time to notification. Therefore, we believe that ContaCT is not substantially similar to an existing technology and meets the newness criterion. We consider the beginning of the newness period to commence on October 1, 2018. We have previously stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53348) and FY 2019 IPPS/LTCH PPS final rule (83 FR 41313), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. Without additional information, we continue to believe that the newness period for ContaCT begins on October 1, 2018. We may consider any further information that may be provided regarding the date of availability in future rulemaking.

We will continue to consider the issues related to determining newness for technologies that use AI, an algorithm or software, including devices classified as radiological computer aided triage and notification software, as discussed in the proposed rule, including how these technologies may be considered or used to identify a unique mechanism of action, how updates to AI, an algorithm or software would affect an already approved technology or a competing technology, whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology, as we gain more experience in this area.

With respect to the cost criterion, the applicant provided the following analysis. First, the applicant extracted claims from the FY 2018 MedPAR dataset. The applicant explained that many patients present to the emergency department with signs or symptoms suggesting an LVO. That presentation would be the basis for ordering a CTA with ContaCT added. Of these patients, some will be identified as stroke and LVO, some as stroke but not from an LVO, and others will have diagnoses completely unrelated to stroke. As a result, according to the applicant, there may be a very broad range of principal diagnoses and MS–DRGs representing patients who would be eligible for and receive a CTA with ContaCT. The applicant noted that it used admitting diagnoses codes rather than principal or secondary diagnosis codes to identify cases of stroke due to LVO, stroke not due to LVO, and no stroke. The applicant utilized a multi-step approach:

- *Step 1:* The applicant first extracted claims from the stroke-related MS–DRGs (023, 024, 061, 062, 063, 064, 065, 066, 067, 068, and 069).
- *Step 2:* The applicant analyzed the admitting diagnosis on claims extracted in Step 1 to identify the reason for admission. The applicant found that the top five admitting diagnoses for patients in the stroke-related MS–DRGs included: Cerebral infarction, unspecified (I63.9), transient cerebral ischemic attack, unspecified (G45.9), slurred speech (R4781), aphasia (R4701), and facial weakness (R29.810).
- *Step 3:* The applicant identified all MS–DRGs assigned to the admitting diagnosis codes identified in Step 2 to identify ContaCT cases that did not map to one of the stroke MS–DRGs.
- *Step 4:* The applicant identified a list of unique MS–DRGs and admitting diagnosis code combinations to which cases involving ContaCT would map. The applicant stated that it reviewed with clinical experts the MS–DRG and admitting diagnosis combinations and eliminated any that were unlikely to include the use of ContaCT.

The applicant identified a total of 375,925 cases across 143 MS–DRGs, with approximately 66 percent of cases mapping to MS–DRGs 039, 057, 064, 065, 066, 069 and 312. The average unstandardized case-weighted charge per case was $52,001. The applicant noted it did not remove any charges for a prior technology, as it asserted that no other technology is comparable to ContaCT. Based on the results of a research study,[28] the applicant assumed ContaCT cases resulting in mechanical thrombectomy would have charges reduced by 38% as a result of reduced specialty care days and therefore removed the related charges, which only affected cases mapping to MS–DRGs 023, 024, 025, and 026. The applicant standardized the charges and applied an inflation factor of 11.1 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629), to update the charges from FY 2018 to FY 2020.

The applicant then added the charges for the new technology. The applicant explained it calculated the cost per patient by dividing the total overall cost of ContaCT per year per hospital by the number of total estimated cases for which ContaCT was used at each hospital that currently subscribes to ContaCT (based on the estimated number of cases receiving CTA), and averaging across all such hospitals. The following is the methodology the applicant used to determine the cost per case:

- *Step 1:* The applicant first determined the estimated total cases (both Medicare and non-Medicare) for each current subscriber hospital. The applicant explained it used total cases for both Medicare and non-Medicare cases since the cost per case is not specific to Medicare cases. In order to determine total cases, which include both Medicare and non-Medicare cases, the applicant divided the total Medicare cases per subscriber hospital from the FY 2018 MedPAR data by the percentage of Medicare beneficiaries (71 percent) in the CONTACT FDA research study (for example, 1,136 Medicare cases divided by 0.71 equals 1,600 total Medicare and non-Medicare cases).
- *Step 2:* To analyze actual rates (percentages) of CTA across subscriber hospital cases, the applicant first used the beneficiary ID in the FY 2018 SAF data set to find matching physician claims in the carrier file for CT and CTA services with a site of service of 21 (Inpatient hospital) or 23 (emergency department) and a date of service consistent with the inpatient stay. The applicant then calculated provider-specific CTA rates (percentages) for each subscriber hospital. The applicant dropped five hospitals with a low volume of Medicare inpatient stays that had no matching services in the carrier file. The applicant calculated an average CTA rate of 21.6 percent across all hospitals that subscribe to ContaCT.

[28] Goldstein ED, Schnusenberg L, Mooney L, et al. Reducing Door-to- Reperfusion Time for Mechanical Thrombectomy With a Multitiered Notification System for Acute Ischemic Stroke. Mayo Clin Proc Innov Qual Outcomes. 2018;2(2): 119–128.

• *Step 3:* The applicant determined the estimated total number of cases that received CTA for each current subscriber hospital by multiplying the total cases (Medicare and non-Medicare) for each subscriber hospital in step 1 by the provider-specific CTA rate calculated in Step 2. In cases where a provider had fewer than 11 cases in the carrier file or where a provider had a CTA rate that was an outlier, the applicant multiplied the total cases for the provider by the average CTA rate of 21.6 percent.

• *Step 4:* The applicant then calculated the cost per year per hospital. If a hospital had multiple sites under the same CCN, the applicant multiplied the total overall cost of ContaCT per hospital by the number of sites. For example, if the cost for ContaCT was $25,000 per year and Hospital A had only one site under its CCN, then the total cost for ContaCT for Hospital A would be $25,000. However, if Hospital B had three sites under its CCN, then the total cost for ContaCT for Hospital B would be $75,000 per year ($25,000 × 3).

• *Step 5:* The applicant then divided the cost per year per hospital by the total cases that received CTA for each customer hospital in Step 3 to determine the estimated cost per case for each customer hospital. If Hospital A from the example in Step 4 had 50 patients, then the total hospital cost per case would be $500 per patient ($25,000/50). If Hospital B (with three sites under its CCN) also had 50 patients, then the total hospital cost per case would be $1,500 per patient ($75,000/50).

• *Step 6:* The applicant averaged the cost per case across all hospitals to determine the average cost per patient. The average cost per case across Hospital A and Hospital B in the previous example would be $1,000.

• *Step 7:* To convert the cost of the technology in Step 6 to charges, the applicant divided the average cost per patient by the national average cost-to-charge (CCR) of 0.14 for the Radiology cost center from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). Although the applicant submitted data related to the cost of the technology, the applicant noted that the cost of the technology was proprietary information.

The applicant calculated a case-weighted threshold amount of $51,358 and a final inflated average case-weighted standardized charge per case of $62,006. Based on this analysis, the applicant asserted that ContaCT meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the case-weighted threshold amount.

The applicant submitted three additional cost analyses to demonstrate that it meets the cost criterion using the same methodology above but with limits on the cases. The first alternative limited the analysis to only those cases in the primary stroke-related MS–DRGs 023, 024, 061, 062, 063, 064, 065, 066, 067, 068, and 069. This first alternative method resulted in a case-weighted threshold of $53,885 and a final inflated average case weighted standardized charge per case of $62,175. The second alternative limited the analysis to cases in MDC 01 (Diseases and Disorders of the Nervous System) with the following MS–DRGs:

MS-DRG	MS-DRG Description
023	Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
024	Craniotomy with Major Device Implant or Acute Complex CNS PDX without MCC
025-027	Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively
037-039	Extracranial Procedures with MCC, with CC, and without CC/MCC, respectively
061-063	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively
064-066	Intracranial Hemorrhage or Cerebral Infarction with MCC, with CC or TPA in 24 hours, and without CC/MCC, respectively
067-068	Nonspecific CVA and Precerebral Occlusion without Infarction with and without MCC, respectively
069	Transient Ischemia without Thrombolytic
091-093	Other Disorders of Nervous System with MCC, with CC, and without CC/MCC, respectively

This second alternative method resulted in a case-weighted threshold of $55,053 and a final inflated average case weighted standardized charge per case of $63,741. The third alternative limited cases to MS–DRGs where the total volume of cases was greater than 100. This third alternative method resulted in a case-weighted threshold of $49,652 and a final inflated average case-weighted standardized charge per case of $59,365. Across all cost-analysis methods, the applicant maintained that the technology meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount.

We noted in the proposed rule that we believe a case weight would provide more accuracy in determining the average cost per case as compared to the average of costs per case across all hospitals that was used by the applicant in Step 6 as summarized previously. We therefore computed a case-weighted cost per case across all current subscriber hospitals. We then inflated the case-weighted cost per case to a charge based on Step 7 above and used this amount in the comparison of the case-weighted threshold amount to the final inflated average case-weighted standardized charge per case (rather than the applicant's average cost per case). In all the scenarios above, the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold amount by an average of $2,961.

We stated in the proposed rule that we had the following concerns regarding whether the technology meets the cost criterion. The applicant used a single list price of ContaCT per hospital

with a cost per patient that can vary based on the volume of cases. We stated that we were concerned that the cost per patient varies based on the utilization of the technology by the hospitals. The cost per patient could be skewed by the small number of hospitals utilizing the technology and their low case volumes. It is possible, if hospitals with large patient populations adopt ContaCT, the cost per patient would be significantly lower.

We stated in the proposed rule that an alternative to the applicant's calculation may be a methodology that expands the applicant's sample from total cases (which include both Medicare and non-Medicare cases) receiving CTA at subscriber hospitals in Step 1 to all inpatient hospitals for the use of ContaCT (and then using the same steps after Step 1 for the rest of the analysis). In this alternative, the applicant would continue to extract cases representing patients that are eligible for the use of ContaCT from MedPAR, but the cost per patient would be determined by dividing the overall cost per year per hospital by the average number of patients eligible for the use of ContaCT across all such hospitals. For example, if the cost for ContaCT is $25,000 per year and the average hospital has 500 patients who are eligible to receive ContaCT per year, then under this alternative methodology, the total cost per patient would be $50 ($25,000/500).

We noted in the proposed rule that if ContaCT were to be approved for new technology add-on payments for FY 2021, we believed the cost per case from the cost analysis above may also be used to determine the maximum new technology add-on payment (that is, 65 percent of the cost determined above). We stated that we understood there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We welcomed comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We also invited public comments on whether the applicant meets the cost criterion.

Comment: One commenter, who was also the applicant, maintained that ContaCT met the cost criterion and submitted two additional analyses following CMS' suggestions in the FY 2021 IPPS/LTCH PPS Proposed Rule.

First, the applicant updated its cost analyses to include all IPPS hospitals, utilizing the same methodology described in detail in the proposed rule. Under this methodology, the cost per patient is calculated by dividing the total overall cost of ContaCT per year per hospital by the number of total estimated cases for which ContaCT would be used at each hospital (based on the estimated number of cases receiving CTA), and then averaging across all such hospitals. The applicant's updated cost analysis included 3,035 Medicare provider numbers representing 3,062 general acute care hospitals. The updated analysis yielded a final inflated average case-weighted standardized charge per case of $71,568, which exceeded the threshold amount of $51,358.

The applicant also updated the three alternative analyses (which used the same methodology as above but limited the cases included) to include all IPPS hospitals. The parameters of these analyses were discussed in detail in the proposed rule (85 FR 32602 through 32603). Per the applicant, the first alternative analysis resulted in a case-weighted threshold of $53,885 and a final inflated average case-weighted standardized charge per case of $71,736; the second alternative analysis resulted in a case-weighted threshold of $55,053 and a final inflated average case weighted standardized charge per case of $73,302; and the third resulted in a case-weighted threshold of $49,652 and a final inflated average case-weighted standardized charge per case of $68,925. In all three alternative analyses, the final average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, meeting the cost criterion.

The applicant also calculated a case-weighted average cost per case for each of the analyses above in response to CMS' suggestion that a case-weighted average cost per case would be more accurate compared to the average of costs per case across all hospitals, as the applicant had done initially. The applicant analyzed the average number of patients eligible to receive ContaCT per hospital among subscribers and compared it to the average number of patients eligible to receive ContaCT among all IPPS hospitals. The applicant found that, among ContaCT subscribers, the average number of patients eligible to receive ContaCT per Medicare provider number and per hospital are 141 and 121, respectively. In contrast, among all IPPS hospitals, the applicant found that the average number of patients eligible to receive ContaCT per Medicare provider number and per hospital are 99 and 82, respectively. The applicant concluded that ContaCT subscribers have a higher average number of patients eligible to receive ContaCT compared to all IPPS hospitals, and that the cost per patient for ContaCT is skewed to yield a higher cost per patient across all IPPS hospitals than among ContaCT subscribers alone. The applicant noted that the cost per patient among ContaCT subscribers is lower than if all IPPS hospitals adopted ContaCT, and that expanding the analyses above to include all IPPS hospitals increased the cost per patient.

Per the applicant, ContaCT would meet the cost criterion in each of these average number of patients eligible to receive ContaCT across all cost-analysis methods. Using a case-weighted cost per case, the applicant also met the cost criterion across all cost-analysis methods, as the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.

The applicant also noted that technologies sold on a subscription basis are provided to the customer at a recurring price at regular intervals. As a result, the cost per unit for a subscription technology is directly impacted not only by the price, but how frequently the customer utilizes the technology, in that customers with low utilization of a subscription-based technology have a higher cost per unit than customers with high utilization. The commenter stated that, because the overall cost per unit of subscription technologies is determined by each customer's ratio of price to utilization, an analysis that requires an estimate of cost per unit should be limited to subscribers. The commenter believed that including estimates of cost per unit for potential customers that do not currently subscribe to the technology may result in a cost-per-case that does not reflect the actual costs of current users. The commenter recommended that the cost per unit of technologies sold on a subscription basis, like ContaCT, should be based on data from current subscribers only. However, the applicant agreed with CMS that yearly updates to the cost per unit analysis are reasonable to reflect changes in subscribers and thus the overall cost per unit.

The commenter offered several examples of how its recommendation is consistent with CMS' methodology in calculating costs across a variety of payment systems and programs. The commenter noted that CMS considers only costs from hospitals for cases billed

to Medicare when setting MS–DRG relative weights. In addition, if a hospital does not provide the type of care described by a specific MS–DRG, CMS does not attempt to estimate what the cost and MS–DRG relative weights might be if a broader range of hospitals delivered that type of care. The commenter stated that another example is the average sales price methodology used by CMS to determine payment for certain separately payable products, which includes only data from actual customer sales. The commenter noted that although the unit price for these products often varies based on utilization, with customers with low utilization paying more per unit than customers with higher utilization, CMS does not attempt to calculate average sales price by forecasting how future customers may alter the current average sales price. The applicant concluded that, consistent with these examples, the cost per unit for subscription technologies should be based on data from current subscribers only and yearly updates are reasonable.

Response: After consideration of the applicant's updated cost analyses for ContaCT, we agree that the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios. Therefore, ContaCT meets the cost criterion for FY 2021. CMS will continue to consider the issues relating to calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area.

With respect to the substantial clinical improvement criterion, according to the applicant, ContaCT represents an advance that substantially improves the ability to diagnose a large vessel occlusion stroke earlier by automatically identifying suspected disease in CTA images and notifying the neurovascular specialist directly in parallel to the standard of care. The applicant further asserted a major limitation in the traditional acute stroke workflow is the time delay from initial image acquisition of a suspected LVO patient (CT, CT angiography, and CT perfusion), notification of the interventional team, and execution of an endovascular thrombectomy. The time from stroke onset to reperfusion (when blood supply returns to tissue after a period of ischemia or lack of oxygen) is negatively correlated with the probability of an independent functional status.[29] The applicant stated the time from initial presentation to eventual reperfusion can be long, resulting in poor outcomes, using the existing standard of care. The median onset-to-revascularization time has been reported as 202.0 minutes for patients presenting directly to interventional centers (or comprehensive stroke centers), and 311.5 minutes for patients that initially presented to a non-interventional center.[30] The applicant further stated that part of that time is the time from initial CTA to the time that the neurovascular specialist is notified of a possible LVO (the CTA to notification time). A retrospective study examined work-flow for stroke patients and demonstrated an initial CT to CSC (Comprehensive Stroke Center) notification time per standard of care >60 minutes in patients transferred for endovascular reperfusion in acute ischemic stroke.[31]

The applicant asserted that ContaCT facilitates a workflow parallel to the standard of care workflow and results in a notified specialist entering the workflow earlier. In the applicant's study to support the De Novo request, ContaCT's performance was compared with standard of care workflow, demonstrating that ContaCT resulted in faster specialist notification. According to the applicant, the average time to specialist notification for ContaCT was 7.32 minutes [95% CI: 5.51, 9.13] whereas time to notification for standard of care workflow was 58.72 minutes [95% CI: 46.21, 71.23]. The applicant also asserted that ContaCT saved an average of 51.4 minutes, an improvement that could markedly improve time to intervention for LVO patients. In addition, the applicant noted that the standard deviation was reduced from 41.14 minutes in the standard of care workflow to 5.95 minutes with ContaCT, demonstrating ContaCT's potential to reduce variation in care and patient outcome across geographies and time of day.[32]

To support the applicant's assertion that ContaCT substantially improves the ability to diagnose a large vessel occlusion stroke earlier, the applicant presented a multicenter prospective observational trial, DISTINCTION, which is ongoing and compares a prospective cohort of patients in which ContaCT is used (intervention arm) to a retrospective cohort in which ContaCT was not used (control arm). Patients are also segmented based on whether they initially present to a non-interventional center or an interventional center. Per the applicant, early data from one non-interventional hospital in the Erlanger Health System indicates that for the control arm the median time from CTA to clinician notification was 59.0 minutes. For the intervention arm, early data indicates that the median time from CTA to clinician notification was 5.3 minutes. The applicant stated that these early data indicate time savings of approximately 53 minutes, which is consistent with the 51.4 minute time savings demonstrated in the studies sponsored/conducted by the De Novo requester.[33]

Next, the applicant presented the Automated Large Artery Occlusion Detection In Stroke Imaging Study (ALADIN), a multicenter retrospective analysis of CTAs randomly picked from a retrospective cohort of acute ischemic stroke patients, with and without anterior circulation LVOs, admitted at three tertiary stroke centers, from 2014–2017. Per the applicant, ALADIN evaluated ContaCT's performance characteristics including area under the curve, sensitivity, specificity, positive predictive value, negative predictive value, and processing or running time. The applicant asserted that, through this study, researchers concluded that the ContaCT algorithm may permit early and accurate identification of LVO stroke patients and timely notification to emergency teams, enabling quick decision-making for reperfusion therapies or transfer to specialized centers if needed.[34] [35] [36]

[29] Khatri P, Abruzzo T, Yeatts SD, et al. Good clinical outcome after ischemic stroke with successful revascularization is time-dependent. *Neurology.* 2009; 73(13):1066–1072.

[30] Froehler MT, Saver JL, Zaidat 00, et al. Interhospital transfer before thrombectomy is associated with delayed treatment and worse outcome in the STRATIS registry. *Circulation.* 2017; 136(24):2311–2321.

[31] Sun CH, Nogueira J, Glenn RG, et al. Picture-to-puncture: A novel time metric to enhance outcomes in patients transferred for endovascular reperfusion in acute ischemic stroke. *Circulation.* 2013; 127:1139–1148.

[32] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[33] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[34] Barreira C, Bouslama M, Lim J, et al. E–108 ALADIN study: Automated large artery occlusion detection in stroke iaging study—a multicenter analysis. *J Neurointerv Surg.* 2018;10(Suppl 2):A101–A102.

[35] Barreira C, Bouslama M, Haussen D, et al. Abstract WP61: Automated large artery occlusion detection in stroke imaging—ALADIN study. *Stroke.* 2018;49:AWP61.

Continued

According to the applicant, the use of ContaCT to facilitate a faster diagnosis and treatment decision directly affects management of the patient by enabling early notification of the neurovascular specialist and faster time to treatment utilizing mechanical thrombectomy to remove the large vessel occlusion. The applicant stated that mechanical thrombectomy with stent retrievers is one of the standards of care for treatment of acute ischemic stroke patients caused by LVO and that mechanical thrombectomy therapy is highly time-critical with each minute saved in onset-to-treatment time resulting in a reported average of 4.2 days of extra healthy life.[37] According to the applicant, the use of ContaCT affects the management of the patient by facilitating early identification of patients with suspected LVO and early notification of the neurovascular specialist. The applicant asserted that this may affect the management of the patient in two ways. First, it may offer improved access to mechanical thrombectomy for patients who would otherwise not have access because of factors such as time of day and the specialty capabilities of the hospital they are in, and second, it may involve the neurovascular team earlier, decreasing the time to thrombectomy. The applicant stated that ContaCT saved an average of 51.4 minutes in time to notification relative to standard of care workflow and reduced standard deviation in time to notification from 41.14 minutes (standard of care workflow) to 5.95 minutes (ContaCT).[38] Furthermore, the applicant stated that ContaCT could markedly improve time to intervention for LVO patients and has the potential to reduce variation in care and patient outcome across geographies and time of day.

The applicant stated that according to five clinical trials, the clinical efficacy of endovascular mechanical thrombectomy has been demonstrated for patients with LVO strokes up to 6 hours after onset of stroke.[39] The applicant also stated that two meta-analyses of these randomized trials have been completed.[40] Campbell et al. performed a patient-level pre-specified pooled meta-analysis of four randomized clinical trials which concluded that thrombectomy for large vessel ischemic stroke is safe and highly effective at reducing disability. Goyal et al. pooled and analyzed patient-level data from all five trials. Per the applicant, the results indicated that mechanical thrombectomy leads to significantly reduced disability. According to the applicant, together, these five randomized trials and two meta-analyses, have demonstrated that treatment for intracranial large vessel occlusion with mechanical thrombectomy with stent retrievers is the standard of care.

The applicant also asserted that real world evidence further supports the efficacy of mechanical thrombectomy. Data from the STRATIS registry (Systematic Evaluation of Patients Treated With Neurothrombectomy Devices for Acute Ischemic Stroke), which prospectively enrolled patients treated in the United States with a Solitaire Revascularization Device and Mindframe Capture Low Profile Revascularization Device within 8 hours from symptom onset, was compared with the interventional cohort from the patient-level meta-analysis from Campbell et al. to assess whether similar process timelines and technical and functional outcomes could be achieved in a large real-world cohort as in the randomized trials. The article concluded that the results indicate randomized trials can be reproduced in the real world (Mueller-Kronast et al., 2017).[41]

The applicant stated that based on these data, U.S. clinical guidelines now recommend mechanical thrombectomy for the treatment of large vessel occlusion strokes when performed ≤6 hours from symptom onset. The American Stroke Association/American Heart Association (ASA/AHA) ''2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke'' recommended mechanical thrombectomy with a stent retriever in patients that meet the following criteria: (1) Prestroke modified Rankin Scale (mRS) 0–1; (2) causative occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA) segment 1 (M1); (3) age ≥18; (4) National Institute of Health Stroke Scale (NIHSS) ≥6; (5) Alberta Stroke Program Early CT Score (ASPECTS) ≥6; and (6) treatment can be initiated within 6 hours of symptom onset (Powers et al., 2018). The ASA/AHA notes the need for expeditious treatment with both intravenous thrombolysis and mechanical thrombectomy.[42]

The applicant also stated that recently, randomized trials have demonstrated the clinical efficacy of mechanical thrombectomy for large vessel occlusion strokes for select patients from 6 to 24 hours after symptom onset.[43] Among patients with acute stroke who were last known well 6 to 24 hours earlier and who had a mismatch between clinical deficit and infarct, outcomes for disability at 90 days were better with thrombectomy plus standard care compared with standard care alone.

The applicant asserted that the use of ContaCT reduces time to treatment by notifying the stroke team faster than the standard of care and enabling the team to diagnose and treat the patient earlier, which is known to improve clinical outcomes in stroke, and that mechanical thrombectomy has been shown to reduce disability, reduce length of stay and recovery time (Campbell et al., 2017).[44]

[36] Rodrigues GM, Barreira CM, Bouslama M, et al. Automated large artery occlusion detection in stroke imaging study (ALADIN). Abstract WP71: Multicenter ALADIN: Automated large artery occlusion detection in stroke imaging using artificial intelligence. *Stroke.* 30 Jan 2019;50:AWP71.

[37] Fransen PS, Berkhemer OA, Lingsma HF, et al. Time to reperfusion and treatment effect for acute ischemic stroke: A randomized clinical trial. *JAMA Neurol.* 2016;73:190–196 ; Meretoja A, Keshtkaran M, Tatlisumak T, Donnan GA and Churilov L. Endovascular therapy for ischemic stroke: save a minute-save a week. *Neurology.* 2017;88(22):2123–2127.

[38] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[39] Berkhemer OA, Fransen PS, Beumer D, et al. MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med.* 2015;372:11–20.doi: 10.1056/NEJMoa1411587; Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med.* 2015;372(11):1009–1018; Jovin TG, Chamorro A, Cobo E, de Miquel MA, Molina CA, Rovira A, et al.; REVASCAT Trial Investigators. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med.* 2015;372(24):2296–2306.

[40] Campbell BC, Hill MD, Rubiera M et al. Safety and efficacy of solitaire stent thrombectomy: Individual patient data meta-analysis of randomized trials. *Stroke.* 2016;47(3):798–806; Goyal M, Menon BK, van Zwam WH, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet N Am Ed.* 2016;387(10029):1723–1731.

[41] Mueller-Kronast NH, Zaidat OO, Froehler MT, et al. Systematic evaluation of patients treated with neurothrombectomy devices for acute ischemic stroke: primary results of the STRATIS registry. *Stroke.* 2017;48(10):2760–2768.

[42] Powers WJ, Rabinstein AA, Ackerson T et al. On behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2018;49:e46–e110.

[43] Albers GW, Marks MP, Kemp S, et al. Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. *N Engl J Med.* 2018;378(8):708–718; Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. *N Engl J Med.* 2018;378(1):11–21.

[44] Campbell BCV, Mitchell PJ, Churilov L, et al. Endovascular Thrombectomy for Ischemic Stroke

According to the applicant, other studies have also demonstrated that time to reperfusion is a predictor of patient outcomes. The applicant asserted that several major randomized controlled trials for mechanical thrombectomy have demonstrated improvements in functionality with faster time to reperfusion. The primary outcome of some of these trials was the modified Rankin scale (mRs) score, a categorical scale measure of functional outcome, with scores ranging from 0 (no symptoms) to 6 (death) at 90 days.[45] Pooled patient-level data from these five trials demonstrated that in the mechanical thrombectomy group the odds of better disability outcomes at 90 days (mRS scale distribution) declined with longer time from symptom onset to expected arterial puncture. Among the mechanical thrombectomy plus medical therapy group patients in whom substantial reperfusion was achieved, delays in reperfusion times were associated with increased levels of 3-month disability.[46]

The applicant referred to the American Stroke Association/American Heart Association (ASA/AHA) ''2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke,'' which recognized that the benefit of mechanical thrombectomy is time dependent, with earlier treatment within the therapeutic window leading to bigger proportional benefits. The guidelines also state that any cause for delay to mechanical thrombectomy, including observing for a clinical response after intravenous alteplase, should be avoided.[47]

The applicant asserted that the phrase ''time is brain'' emphasizes that human nervous tissue is rapidly lost as stroke progresses. Per the applicant, recent advances in quantitative neurostereology and stroke neuroimaging permit calculation of just how much brain is lost per unit time in acute ischemic stroke. To illustrate this point, the applicant stated that in the event of a large vessel acute ischemic stroke, the typical patient loses 1.9 million neurons, 13.8 billion synapses, and 12 km (7 miles) of axonal fibers each minute in which stroke is untreated. Furthermore, for each hour in which treatment fails to occur, the brain loses as many neurons as it does in almost 3.6 years of normal aging.[48] The applicant asserted that given the time-dependent nature of treatment in acute ischemic stroke patients, ContaCT could play a critical role in preserving human nervous tissue, as the application results in faster detection in more than 95 percent of cases and saves an average of 51.4 minutes in time to notification.[49]

We stated in the proposed rule that we had the following concerns regarding whether the technology meets the substantial clinical improvement criterion. The applicant provided a total of 19 articles specifically for the purposes of addressing the substantial clinical improvement criterion: four retrospective studies/analyses, nine randomized clinical trials (RCTs), three meta-analyses, one registry, one guideline, and one systematic review.

The four retrospective studies/analyses included the FDA decision memorandum, a single site of a RCT, and two abstracts related to the Automated Large Artery Occlusion Detection in Stroke Imaging (ALADIN) study. The applicant stated that the studies sponsored/conducted by the De Novo requester indicated that ContaCT substantially shortens the time to notifying the specialist for LVO cases as compared with the standard of care. However, the sample size was limited to only 85 out of 300 patients having sufficient data of CTA to notification time available. To calculate the sensitivity and specificity of ContaCT, neuro-radiologists reviewed images and established the empirical evidence. Specifically, the sensitivity and specificity was 87.8 percent (95% CI: 81.2–92.5%) and 89.6 percent (83.7–93.9%), respectively. In the proposed rule, we stated that we had concerns regarding whether this represents a substantial clinical improvement, as ContaCT missed approximately 12 percent of images with a true LVO and incorrectly identified approximately 10 percent as having an LVO. Additionally, the small sample size of less than 100 raises concerns for generalizability. Additionally, we agree with the FDA that ContaCT is limited to analysis of imaging data and should not be used in lieu of full patient evaluation or relied upon to make or confirm diagnosis.[50]

With respect to the study that was a single site of an RCT[51] presented by the applicant, the study conducted a retrospective review of the time between an initial CT at an outside hospital and the notification to the comprehensive stroke center. This retrospective analysis was conducted for one site enrolled in one of the RCTs (unspecified). The authors noted there was substantial difference in the time between initial CT at the outside hospital to comprehensive stroke center notification, due to multiple factors, including delays in neurological assessments, interpretation of imaging, utilization of advance modality imaging, and determination of tPA effectiveness. Specifically, the authors noted in their study that obtainment of advanced imaging contributed to a 57-minute delay in decision making without substantial benefits in patient outcome. We stated in the proposed rule that it was unclear whether and how this time delay and the utilization of faster notification would affect the clinical outcome of patients.

The applicant also submitted two separate abstracts for a retrospective analysis of the ALADIN study, which only provide interim results. The applicant noted for the primary analysis, the algorithm obtained sensitivity of 0.97 and specificity of 0.52, with a positive predictive value (PPV) of 0.74 and negative predictive (NPV) of 0.91, and overall accuracy of

Increases Disability-Free Survival, Quality of Life, and Life Expectancy and Reduces Cost. *Front Neurol.* 2017;8:657.

[45] Berkhemer OA, Fransen PS, Beumer D, et al. MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med.* 2015;372:11–20.doi: 10.1056/NEJMoa1411587; Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med.* 2015;372(11):1009–1018; Goyal M, Demchuk AM, Menon BK, Eesa M, Rempel JL, Thornton J, et al.; ESCAPE Trial Investigators. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J* Med. 2015;372(11):1019–1030; Jovin TG, Chamorro A, Cobo E, de Miquel MA, Molina CA, Rovira A, et al.; REVASCAT Trial Investigators. Thrombectomy within 8 hours after symptom onset in ischemic stroke. N Engl J Med. 2015;372(24):2296–2306; Saver JL, Goyal M, Bonafe A, Diener HC, Levy EI, Pereira VM, et al.; SWIFT PRIME Investigators. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N Engl J Med. 2015 Jun 11;372(24):2285–95.

[46] Saver JL, Goyal M, van der Lugt A, et al.; HERMES Collaborators. Time to treatment with endovascular thrombectomy and outcomes from ischemic stroke: a meta-analysis. *JAMA.* 2016;316:1279–1288.

[47] Powers WJ, Rabinstein AA, Ackerson T et al. On behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2018;49:e46–e110.

[48] Saver JL. Time is brain—quantified. *Stroke.* 2006 Jan;37(1):263–6.

[49] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for Contact. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[50] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[51] Sun CH, Nogueira J, Glenn RG, et al. Picture-to-puncture: A novel time metric to enhance outcomes in patients transferred for endovascular reperfusion in acute ischemic stroke. *Circulation.* 2013;127:1139–1148.

0.78. For the secondary analysis, which included analysis of additional (secondary) vessels, the algorithm obtained sensitivity of 0.92 and specificity of 0.75, with a PPV of 0.92 and NPV of 0.75, and overall accuracy of 0.88. In the proposed rule, we stated that we were concerned both that these are only partial results as it is not clear what the full outcome of the ALADIN study will indicate, and also that the initial overall accuracy of ContaCT varied by 10 percent between the types of strokes.

The RCTs included the following: (1) Multicenter Randomized Clinical Trial of Endovascular Treatment of Acute Ischemic Stroke in the Netherlands (MR CLEAN);(2) Thrombolysis in Emergency Neurological Deficits—Intra-Arterial (EXTEND–IA) Trial; (3) The Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times (ESCAPE) trial; (4) Randomized Trial of Revascularization with Solitaire FR Device versus Best Medical Therapy in the Treatment of Acute Stroke Due to Anterior Circulation Large Vessel Occlusion Presenting within Eight Hours of Symptom Onset (REVASCAT); (5) Solitaire with the Intention for Thrombectomy as Primary Endocascular Treatment (SWIFT PRIME) trial; (6) Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke; (7) DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) trial; and (8) Interventional Manage of Stroke (IMS) Phase I and II trials. The MR CLEAN trial, EXTEND–IA trial, ESCAPE trial, REVASCAT trial, SWIFT PRIME trial, Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke trial, and DAWN were all multicenter prospective RCTs evaluating a treatment group of either a microcatheter with a thrombolytic agent or mechanical thrombectomy versus a control group of the standard of care. These RCTs were evaluating the outcomes from specific treatment for patients who suffered from various strokes and not the time of imaging to treatment. While each study may have included a time-element as an experimental analysis or additional end-point, we stated that we are unsure how they support the use of ContaCT as a substantial clinical improvement over existing technologies. Also, while the IMS trials provided evidence to support a positive clinical outcome following technically successful angiographic reperfusion using time from stroke onset to procedure termination, they did not specify which part of the overall standard of care treatment affected an increase or decrease of time. The three meta-analyses utilized data from the RCTs. The Safety and Efficacy of Solitaire Stent Thrombectomy examined four trials, ESCAPE, REVASCAT, SWIFT PRIME, and EXTEND–IA. The Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke Trials (HERMES) collaboration authored two of the three meta-analyses. The HERMES collaboration examined data and results from five RCTs, MR CLEAN, ESCAPE, REVASCAT, SWIFT PRIME, and EXTEND–IA. These meta-analyses confirmed the results of each of the individual RCTs of the benefits of thrombectomy versus the standard of care. However, we stated that we have concerns as to whether these meta-analyses, along with the RCTs, indicate a substantial clinical improvement with shorter notification times of an LVO.

Two articles submitted by the applicant evaluated data using the STRATIS registry. One article [52] evaluated the use of mechanical thrombectomy in consecutive patients with acute ischemic stroke because of LVO in the anterior circulation. The two groups consisted of (1) patients who presented directly to a comprehensive stroke center; and (2) patients who were transferred to a comprehensive stroke center. This study identified a difference of 124 minutes between groups, which was primarily related to longer door-to-tPA times at nonenrolling hospitals, delay between IV-tPA and departure from the initial hospital, and length of transport time. The author's primary outcome was functional status at 90 days, which found those with shorter time to treatment achieved better functional independence at 90 days. There was no difference in mortality in the two groups. While this article supports that shorter time to treatment may increase positive clinical outcomes for functional status, the study indicated time to departure from the non-enrolling hospital and transfer time as primary reasons in delayed thrombectomy treatment. These two time lapses include multiple covariates; for example, the distance between the facilities and the response of available transport (for example, ambulance). We stated in the proposed rule that these potential confounders raise questions as to the use of ContaCT shortening time to treatment.

Lastly, the applicant submitted the AHA/ASA guidelines and a systematic literature review as support for clinical improvement. We stated that we are concerned the guidelines do not support a finding of substantial clinical improvement for ContaCT because the guidelines are for the current standard of care. The systematic literature review identified the quantitative estimates of the pace of neural circuity loss in human ischemic stroke. While this supports the urgency of stroke care, we stated that we were unsure how it demonstrates a substantial clinical improvement in how ContaCT supports the urgency of stroke care.

We invited public comment as to whether ContaCT meets the substantial clinical improvement criterion.

Comment: In addressing substantial clinical improvement concerns raised by CMS in the proposed rule, the applicant summarized additional clinical evidence demonstrating ContaCT reduces time to notification, and that the device also reduces time to treatment and improves clinical outcomes.

With respect to improved clinical outcomes, the applicant described a study submitted for publication that used a prospectively-maintained database of patients undergoing thrombectomy for LVO and assessed the impact of ContaCT implementation on door-to-treatment time and patient outcomes for all patients who presented to a Primary Stroke Center currently utilizing ContaCT in the Mount Sinai Health System in New York and who subsequently underwent mechanical thrombectomy. To evaluate impact in a controlled fashion, data from pre-ContaCT implementation (October 1, 2018 to March 15, 2019) and post-ContaCT implementation (October 1, 2019 to March 15, 2020) were compared from a total of 42 patients who met the inclusion criteria. According to the applicant, the study investigators found that the post-ContaCT cohort had significantly better clinical outcomes and level of disability, as measured by a lower 5-day NIH Stroke Scores (NIHSS) and lower discharge modified Rankin Score (mRS) scores compared to the pre-ContaCT cohort, 10.78 vs. 21.93 (p=0.02) and 2.92 vs. 4.62 (p=0.03), respectively. The post-ContaCT cohort also demonstrated significantly lower median 90-day mRS scores compared to the pre-ContaCT cohort (3 vs. 5; p=0.02). In addition to these outcome measures, the post-ContaCT cohort also had significantly shorter median door-to-interventional radiologist (INR)

[52] Froehler MT, Saver JL, Zaidat 00, et al. Interhospital transfer before thrombectomy is associated with delayed treatment and worse outcome in the STRATIS registry. *Circulation.* 2017; 136(24):2311–2321.

notification time (21.5 vs. 36 minutes, p=0.02) and shorter median door-to-puncture time (165 vs. 185 minutes, p=0.20).

With respect to shorter time to treatment, the applicant summarized unpublished data from three distinct single center, retrospective investigator-initiated reviews from hospital systems that have implemented ContaCT in Colorado, Georgia, and Tennessee. The three reviews evaluated ContaCT's impact on the time from hospital arrival (Door) to skin puncture (Puncture), or DTSP, for LVO patients initially presenting to the clinical site.

At the first site, 32 patients initially presented to the emergency department at SkyRidge Medical Center in Colorado. Patients included in the analysis were divided into two cohorts. The pre-ContaCT cohort included the 16 thrombectomy patients immediately preceding ContaCT implementation and the post-ContaCT cohort included the 16 thrombectomy patients immediately after ContaCT implementation. Overall, ContaCT implementation resulted in an average reduction in door-to-puncture time of 24 minutes. Additionally, ContaCT implementation resulted in statistically significant improvements in the percentage of patients with door to puncture times of less than 90 minutes (p=0.013) and less than 60 minutes (p=.005). After installing ContaCT, 94 percent of thrombectomy cases had DTSP <90 minutes (p=0.013).

At the second site, 120 patients initially presented to the emergency department at Wellstar Hospital in Georgia. Patients included in the analysis were divided into two cohorts. Patients from pre-ContaCT implementation (July 2018 through June 2019) and patients from post-ContaCT implementation (July 2019 to June 2020) were compared. Overall, ContaCT implementation resulted in an average reduction in door to puncture time of 30 minutes (p=0.01).

At the third site, 46 patients initially presented to a Primary Stroke Center currently utilizing ContaCT in the Methodist LeBonheur Healthcare System in Tennessee. Patients included in the analysis were divided into two cohorts: Patients with LVOs identified by ContaCT and patients with LVOs not identified by ContaCT. Overall, ContaCT implementation resulted in an average reduction in door-to-puncture time of 44 minutes (p=0.03).

With respect to shorter time to notification, the applicant described data maintained by Viz.ai indicating that real-world performance of ContaCT is consistent with the results achieved in the FDA clinical study. Across 4,763 patients analyzed by ContaCT in the past six months, the median time from CT angiogram to notification of the specialist was 4.31 minutes. This compares with 5.6 minutes in the ContaCT cohort (compared with 58.7 minutes in the standard of care cohort) in the FDA clinical trial. The percentage of notifications viewed by the specialist within five minutes was 90 percent in the same cohort of patients.

In addressing concerns raised by CMS in the proposed rule regarding whether the clinical study supporting the applicant's De Novo request for ContaCT represents a substantial clinical improvement, the applicant stated that the sensitivity and specificity (87% and 90%, respectively) of ContaCT are consistent with the performance characteristic for other diagnostic services that inform clinical care and that no tests have perfect performance. Moreover, the applicant stated that because ContaCT is a triage and notification system, no harm is expected to result from false positives or false negatives. ContaCT will triage and alert on false positives resulting in an earlier read of the CT angiogram image than what otherwise would be and are quickly reviewed and appropriately triaged to non-treatment. False negatives, when no alert is sent, are managed exactly the same as today's standard of care without ContaCT, as no alert is sent in the standard of care. The applicant noted the benefit for patients with LVO that are correctly identified by ContaCT (true positives).

In addressing concerns raised by CMS in the proposed rule regarding whether the results of the clinical study supporting the applicant's De Novo request for ContaCT are generalizable, the applicant stated that data maintained by Viz.ai (and referenced above) suggest that real-world performance of ContaCT is even faster than what was found in the FDA clinical trial. According to the applicant, these internal data are supported by the additional clinical evidence provided to CMS that demonstrate not only does ContaCT reduce time to notification of the neurointerventionalist, it reduces time to treatment and improves clinical outcomes as demonstrated by lower 5-day NIHSS and lower discharge mRS.

The applicant also addressed concerns noted by CMS that results provided in the new technology application from the ALADIN study were partial results and showed somewhat more variable accuracy estimates than the FDA study. The applicant stated that complete results from the ALADIN study were unnecessary to support the performance of the ContaCT system as the primary objective of the ALADIN study was to fine-tune and optimize the ContaCT algorithm prior to the FDA study. According to the applicant, the best and most reliable data on the performance of the ContaCT device is the data from the pivotal study conducted for and submitted to the FDA as part of the *de novo* classification request.

In the proposed rule, CMS pointed to the multiple steps and variables that impact time to treatment and clinical outcomes in LVO, questioning the ability of ContaCT to shorten time to treatment. In their comment, the applicant stated that the existence of other variables that impact time to treatment and clinical outcomes does not preclude clinical benefits from one variable, such as time to notification. The applicant stated that alerting the stroke specialist earlier than the standard of care enables them to make treatment decisions earlier, shortening the amount of time to treatment and improving clinical outcomes.

The applicant also addressed CMS' concern about whether and how utilization of faster analysis and notification of suspected LVOs derived from CTA images would affect the clinical outcome of patients, considering evidence demonstrating that obtainment of advanced imaging like CTA contributed to a 57-minute delay in decision making.[53] The applicant stated that AHA's ''2019 Update to the 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke'' recommend vessel imaging, such as CTA, for patients with suspected LVOs.[54] Furthermore, according to the applicant, the AHA's broad recommendations supporting vessel imaging are consistent with requirements of pivotal trials for mechanical thrombectomy, all of which required noninvasive CTA or MR angiography (MRA) diagnosis of LVO as an inclusion criterion. Additionally, secondary analyses from the Interventional Management of Stroke (IMS) III Trial, which helped established vessel imaging as standard of care in

[53] Sun CH, Nogueira J, Glenn RG, et al. Picture-to-puncture: A novel time metric to enhance outcomes in patients transferred for endovascular reperfusion in acute ischemic stroke. *Circulation.* 2013;127:1139–1148.

[54] Powers WJ, Rabinstein AA, Ackerson T, et al; on behalf of the American Heart Association Stroke Council. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

stroke imaging,[55] found that use of CTA with or without CT perfusion did not delay IV-tPA or endovascular therapy as compared to non-contrast CT in the IMS III trial.[56]

Finally, with regards to CMS' concerns about whether ContaCT provides substantial clinical improvement, the applicant stated that all available clinical guidelines support faster time to treatment. They reiterated that the importance of time in stroke care is well established, and that reducing time to treatment improves clinical outcomes. They asserted that the new clinical evidence provided in their comment demonstrated the direct effect that ContaCT has on both time to treatment and patient outcomes and they maintained that these data are consistent with a well-established body of evidence that reduced time to notification and treatment of LVO improves outcomes in patients with ischemic stroke.

We also received comments from many other commenters expressing their support for new technologies that reduce time to treatment for stroke patients, noting that rapid identification and treatment of these patients at comprehensive stroke centers offers the possibility to minimize the stroke burden and deficit and maximize the potential of a good outcome and return to function. Several commenters also recognized that rapid triaging of stroke patients has been endorsed as a best practice in published clinical guidelines. Some commenters supported the use of AI in the care of stroke patients and neuroscience patients generally, but did not endorse a particular technology, device, product, or manufacturer.

Several commenters noted their direct experience with ContaCT upon implementation of the new technology at their hospitals, asserting that communication between all providers involved in the acute care of patients with stroke has significantly improved. A commenter stated that the ContaCT triage and notification system directly saved the lives of many patients at their hospital. The commenter referenced that their hospital team performed analyses which demonstrated that the use of the ContaCT system resulted in a statistically significant improvement on transfer patient outcomes. Another commenter experienced with the ContaCT system stated it led to a dramatic improvement in patient workflow for acute stroke patients and has significantly decreased door-in door-out times for patients needing emergent treatment who present to spoke hospitals, improved decision times for ''go'' or ''no go'' for endovascular therapy at patients presenting to both spoke and hub hospitals, and has led to improved overall outcomes of patients.

Some commenters stated that rapid identification of stroke patients is especially pressing at smaller hospitals that are trying their best to transfer stroke patients to the nearest stroke center. A commenter noted that the reduction of time to treatment by ContaCT is leading to better outcomes clinically, less societal drain of resources, and fewer financial burdens to families requiring the incomes of the patients suffering from stroke disability. Another commenter asserted that if ContaCT receives approval for add-on payments, more hospitals would be able to implement this technology and, as a result, more patients would have access to life saving treatment, leading to a significant reduction of disability from stroke. According to the commenter, allowing hospitals to receive reimbursement for ContaCT would not only benefit communities in large metro areas but, more importantly, in rural areas where access to stroke care and technology is limited due to limited resources.

Response: We appreciate the commenters' input, including the additional information and analysis provided by the applicant in response to our concerns regarding substantial clinical improvement. After reviewing the additional clinical information and other analysis submitted by the applicant in response to our concerns raised in the proposed rule, we have determined that ContaCT represents a substantial clinical improvement over existing technologies because, based on the information provided by the applicant, the technology shortens time to notification, which has been shown in some instances to be critical in improving long-term outcomes in the treatment of stroke.

After consideration of the public comments we received, we have determined that ContaCT meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for ContaCT for FY 2021. Cases involving the use of ContaCT that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code 4A03X5D.

In its application, the applicant stated that the cost per patient of ContaCT will vary based on the number of cases. As discussed previously, per the applicant, the cost per patient is calculated based on the annual list price of ContaCT multiplied by the number of subscribers, and divided by the number of ContaCT cases across such subscribers. We noted that, if ContaCT were to be approved for new technology add-on payments for FY 2021, we believed the cost per case from the applicant's original cost analysis above may also be used to determine the maximum new technology add-on payment (that is, 65 percent of the cost determined above). The applicant estimated that the average cost of ContaCT to the hospital is $1,600 based on customer data. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the costs of the new medical service or technology, or 65 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, the maximum new technology add-on payment for a case involving the use of ContaCT is $1,040 for FY 2021.

d. Supersaturated Oxygen (SSO_2) Therapy (DownStream® System)

TherOx, Inc. submitted an application for new technology add-on payments for Supersaturated Oxygen (SSO_2) Therapy (the TherOx DownStream® System) for FY 2021. We note that the applicant previously submitted an application for new technology add-on payments for FY 2019, which was withdrawn prior to the issuance of the FY 2019 IPPS/LTCH PPS final rule. We also note that the applicant again submitted an application for new technology add-on payments for FY 2020, but CMS was unable to determine that SSO_2 Therapy represents a substantial clinical improvement over the currently available therapies used to treat STEMI patients.

Per the applicant, The DownStream® System is an adjunctive therapy that creates and superoxygenated arterial blood and delivers it directly to reperfused areas of myocardial tissue which may be at risk after an acute myocardial infarction (AMI), or heart attack. Per FDA, SSO_2 Therapy is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO_2 Therapy) to targeted ischemic regions perfused by the patient's left anterior descending coronary artery immediately following revascularization by means of

[55] Menon BK, Qazi E, Nambiar V, et al.; for the Interventional Management of Stroke III Investigators. Differential effect of baseline computed tomographic angiography collaterals on clinical outcome in patients enrolled in the Interventional Management of Stroke III Trial. *Stroke.* 2015; 46:1239–1244.

[56] Vagal A, Foster LD, Menon B, et al. Multimodal CT Imaging: Time to Treatment and Outcomes in the IMS III Trial. *AJNR Am J Neuroradiol.* 2016;37(8):1393–1398.

percutaneous coronary intervention (PCI) with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction (AMI) symptoms caused by a left anterior descending artery infarct lesion. The applicant stated that the net effect of the SSO_2 Therapy is to reduce the size of the infarction and, therefore, lower the risk of heart failure and mortality, as well as improve quality of life for STEMI patients.

SSO_2 Therapy consists of three main components: The DownStream® System; the DownStream cartridge; and the SSO_2 delivery catheter. The DownStream® System and cartridge function together to create an oxygen-enriched saline solution called SSO_2 solution from hospital-supplied oxygen and physiologic saline. A small amount of the patient's blood is then mixed with the SSO_2 solution, producing oxygen-enriched hyperoxemic blood, which is delivered to the left main coronary artery (LMCA) via the delivery catheter at a flow rate of 100 ml/min. The duration of the SSO_2 Therapy is 60 minutes and the infusion is performed in the catheterization laboratory. The oxygen partial pressure (pO_2) of the infusion is elevated to ~1,000 mmHg, therefore providing oxygen locally to the myocardium at a hyperbaric level for 1 hour. After the 60-minute SSO_2 infusion is complete, the cartridge is unhooked from the patient and discarded per standard practice. Coronary angiography is performed as a final step before removing the delivery catheter and transferring the patient to the intensive care unit (ICU).

The applicant for the SSO_2 Therapy received premarket approval from FDA on April 2, 2019. FDA noted the applicant must conduct ''a post-approval study to confirm the safety and effectiveness of the TherOx DownStream System for use of delivery of SuperSaturated Oxygen Therapy (SSO_2 Therapy) to targeted ischemic regions of the patient's coronary vasculature in qualifying anterior acute myocardial infarction (AMI) patients who have undergone successful percutaneous coronary intervention (PCI) with stenting within 6 hours of experiencing AMI symptoms.'' [57] The applicant stated that use of the SSO_2 Therapy can be identified by the ICD–10–PCS procedure codes 5A0512C (Extracorporeal supersaturated oxygenation, intermittent) and 5A0522C (Extracorporeal supersaturated oxygenation, continuous).

[57] *https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170027A.pdf.*

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would therefore not be considered ''new'' for purposes of new technology add-on payments. We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42275), we stated that based on the information submitted by the applicant as part of its FY 2020 new technology add-on payment application for SSO_2 Therapy, as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19353), and as summarized in the FY 2020 IPPS/LTCH PPS final rule, we believe that SSO_2 Therapy has a unique mechanism of action as it delivers a localized hyperbaric oxygen equivalent to the coronary arteries immediately after administering the standard-of-care, PCI with stenting, in order to restart metabolic processes within the stunned myocardium and reduce infarct size. Therefore, we stated that we believe SSO_2 Therapy is not substantially similar to existing technologies and meets the newness criterion. We also stated that we would consider the beginning of the newness period to commence when SSO_2 Therapy was approved by the FDA on April 2, 2019. We refer the reader to the FY 2020 final rule for the complete discussion of how SSO_2 Therapy meets the newness criterion. We invited public comments on whether SSO_2 Therapy is substantially similar to an existing technology and whether it meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021.

Comment: Several commenters, including the applicant, agreed with CMS' assessment in the FY 2020 IPPS/LTCH PPS final rule that SSO_2 Therapy meets the newness criterion and is not substantially similar to existing technologies. These commenters stated their belief that SSO_2 Therapy is a novel and efficacious therapy with a unique mechanism of action. The commenters stated that the current standard of care does not address myocardial tissue death and scarring, which is often linked to increased risk of heart failure and long-term mortality.

Response: We appreciate the commenters' support.

Based on consideration of the comments received and information submitted by the applicant as part of its FY 2021 new technology add-on payment application for SSO_2 Therapy, as discussed in the proposed rule (85 FR 32608–32609) and previously summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42274–42275), we believe that SSO_2 Therapy does not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared to existing treatments. Therefore, we believe that SSO_2 Therapy is not substantially similar to an existing technology and meets the newness criterion. We consider the beginning of the newness period to commence when SSO_2 Therapy was approved by the FDA on April 2, 2019.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that SSO_2 Therapy meets the cost criterion. The applicant searched the FY 2018 MedPAR file for claims reporting diagnoses of anterior STEMI by ICD–10–CM diagnosis codes I21.01 (ST elevation (STEMI) myocardial infarction involving left main coronary artery), I21.02 (ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery), or I21.09 (ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall) as a principal diagnosis, which the applicant believed would describe potential cases representing potential patients who may be eligible for treatment involving the SSO_2 Therapy. The applicant identified 9,111 cases mapping to 4 MS–DRGs, with approximately 95 percent of all potential cases mapping to MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries/Stents) and MS–DRG 247 (Percutaneous Cardiovascular Procedures with -DrugEluting- Stent without MCC). The remaining 5 percent of potential cases mapped to MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries/Stents) and MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC).

The applicant determined that the average case-weighted unstandardized charge per case was $97,049. The applicant then standardized the charges. The applicant did not remove charges for the current treatment because, as previously discussed, SSO_2 Therapy would be used as an adjunctive treatment option following successful PCI with stent placement. The applicant then added charges for the technology, which accounts for the use of 1 cartridge per patient, to the average charges per case. The applicant did not apply an inflation factor to the charges for the technology. The applicant also added charges related to the technology, to account for the additional supplies used in the administration of SSO_2 Therapy, as well as 70 minutes of procedure room

time, including technician labor and additional blood tests. The applicant inflated the charges related to the technology. In the applicant's analysis, the inflated average case-weighted standardized charge per case was $150,115 and the average caseweighted-threshold amount was $98,332. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We invited public comments on whether the SSO_2 Therapy meets the cost criterion.

Comment: One commenter, who is also the applicant, supported CMS' conclusion in the FY 2020 IPPS/LTCH PPS final rule that SSO_2 Therapy meets the cost criterion, based on an analysis of the 2017 MedPAR file which yielded an inflated case-weighted standardized charge per case that exceeded the average case-weighted threshold amount. Other commenters stated their belief that SSO_2 Therapy is inadequately paid under the MS–DRGs noted in the application. These commenters urged CMS to approve SSO_2 Therapy for new technology add-on payments to ensure access to Medicare beneficiaries.

Response: Based on the applicant's cost analysis as previously summarized and consideration of the comments received, we agree that the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, SSO_2 Therapy meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SSO_2 Therapy represents a substantial clinical improvement over existing technologies because it improves clinical outcomes for STEMI patients as compared to the currently available standard-of-care treatment, PCI with stenting alone. Specifically, the applicant asserted that: (1) Infarct size reduction improves mortality outcomes; (2) infarct size reduction improves heart failure outcomes; (3) SSO_2 Therapy significantly reduces infarct size; (4) SSO_2 Therapy prevents left ventricular dilation; and (5) SSO_2 Therapy reduces death and heart failure at 1 year. The applicant highlighted the importance of the SSO_2 Therapy's mechanism of action, which treats hypoxemic damage at the microvascular or microcirculatory level. Specifically, the applicant noted that microvascular impairment in the myocardium is irreversible and leads to a greater extent of infarction. According to the applicant, the totality of the data on myocardial infarct size, ventricular remodeling, and clinical outcomes strongly supports the substantial clinical benefit of SSO_2 Therapy administration over the SOC.

As stated above, TherOx, Inc. submitted an application for new technology add-on payments for FY 2020 that was denied on the basis of substantial clinical improvement. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42278), we stated that we were not approving new technology add-on payments for SSO_2 Therapy for FY 2020 because, after consideration of the comments received, we remained concerned that the current data did not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represents a substantial clinical improvement over existing available options. The applicant resubmitted its application for new technology add-on payments for FY 2021 with new information that, per the applicant, demonstrates that there is an unmet medical need for STEMI, and that SSO_2 Therapy provides a treatment option for a patient population unresponsive to currently available treatments. Below we summarize the studies the applicant submitted with both its FY 2020 and FY 2021 applications, followed by the new information the applicant submitted with its FY 2021 application to support that the technology represents a substantial clinical improvement.

In the FY 2020 application, as summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42275), and the FY 2021 application, the applicant cited an analysis of the Collaborative Organization for RheothRx Evaluation (CORE) trial and a pooled patient-level analysis to support the claims that infarct size reduction improves mortality and heart failure outcomes.

- The CORE trial was a prospective, randomized, double-blinded, placebo-controlled trial of Poloxamer 188, a novel therapy adjunctive to thrombolysis at the time the study was conducted.[58] The applicant sought to relate left ventricular ejection fraction (EF), end-systolic volume index (ESVI) and infarct size (IS), as measured in a single, randomized trial, to 6-month mortality after myocardial infarction treated with thrombolysis. According to the applicant, subsets of clinical centers participating in CORE also participated in one or two radionuclide sub-studies: (1) Angiography for measurement of EF and absolute, count-based LV volumes; and (2) single-photon emission computed tomographic sestamibi measurements of IS. These sub-studies were performed in 1,194 and 1,181 patients, respectively, of the 2,948 patients enrolled in the trial. Furthermore, ejection fraction, ESVI, and IS, as measured by central laboratories in these sub-studies, were tested for their association with 6-month mortality. According to the applicant, the results of the study showed that ejection fraction (n=1,137; p=0.0001), ESVI (n=945; p=0.055) and IS (n=1,164; p=0.03) were all associated with 6-month mortality, therefore, demonstrating the relationship between these endpoints and mortality.[59]
- The pooled patient-level analysis was performed from 10 randomized, controlled trials (with a total of 2,632 patients) that used primary PCI with stenting.[60] The analysis assessed infarct size within 1 month after randomization by either cardiac magnetic resonance (CMR) imaging or technetium-99m sestamibi single-photon emission computed tomography (SPECT), with clinical follow-up for 6 months. Infarct size was assessed by CMR in 1,889 patients (71.8 percent of patients) and by SPECT in 743 patients (28.2 percent of patients) including both inferior wall and more severe anterior wall STEMI patients. According to the applicant, median infarct size (or percent of left ventricular myocardial mass) was 17.9 percent and median duration of clinical follow-up was 352 days. The Kaplan-Meier estimated 1-year rates of all-cause mortality, re-infarction, and HF hospitalization were 2.2 percent, 2.5 percent, and 2.6 percent, respectively. The applicant noted that a strong graded response was present between infarct size (per 5 percent increase) and the 2 outcome measures of subsequent mortality (Cox-adjusted hazard ratio: 1.19 [95 percent confidence interval: 1.18 to 1.20]; p<0.0001) and hospitalization for heart failure (adjusted hazard ratio: 1.20 [95 percent confidence interval: 1.19 to 1.21]; p<0.0001), independent of other baseline factors.[61] The applicant concluded from this study that infarct size, as measured by CMR or technetium-99m sestamibi SPECT within 1 month after primary PCI, is strongly associated with all-cause

[58] Burns, R.J., Gibbons, R.J., Yi, Q., et al., ''The relationships of left ventricular ejection fraction, end-systolic volume index and infarct size to six-month mortality after hospital discharge following myocardial infarction treated by thrombolysis,'' *J Am Coll Cardiol,* 2002, vol. 39, pp. 30–6.

[59] Ibid.

[60] Stone, G.W., Selker, H.P., Thiele, H., et al., ''Relationship between infarct size and outcomes following primary PCI,'' *J Am Coll Cardiol,* 2016, vol. 67(14), pp. 1674–83.

[61] Ibid.

mortality and hospitalization for heart failure within 1 year.

In the FY 2020 application, the applicant also cited the AMIHOT I and II studies to support the claim that SSO_2 Therapy significantly reduces infarct size.

- The AMIHOT I clinical trial was designed as a prospective, randomized evaluation of patients who had been diagnosed with AMI, including both anterior and inferior patients, and received treatment with either PCI with stenting alone or with SSO_2 Therapy as an adjunct to successful PCI within 24 hours of symptom onset.[62] The study included 269 randomized patients and 3 co-primary endpoints: Infarction size reduction, regional wall motion score improvement at 3 months, and reduction in ST segment elevation. The study was designed to demonstrate superiority of the SSO_2 Therapy group as compared to the control group for each of these endpoints, as well as to demonstrate non-inferiority of the SSO_2 Therapy group with respect to 30-day Major Adverse Cardiac Event (MACE). The applicant stated that results for the control versus SSO_2 Therapy group comparisons for the three co-primary effectiveness endpoints demonstrated a nominal improvement in the test group, although this nominal improvement did not achieve clinical and statistical significance in the entire population. The applicant further stated that a pre-specified analysis of the SSO_2 Therapy patients who were revascularized within 6 hours of AMI symptom onset and who had anterior wall infarction showed a marked improvement in all 3 co-primary endpoints as compared to the control group.[63] Key safety data revealed no statistically significant differences in the composite primary endpoint of 1-month (30 days) MACE rates between the SSO_2 Therapy and control groups. MACE includes the combined incidence of death, re-infarction, target vessel revascularization, and stroke. In total, 9/134 (6.7 percent) of the patients in the SSO_2 Therapy group and 7/135 (5.2 percent) of the patients in the control group experienced 30-day MACE (p=0.62).[64]

- The AMIHOT II trial randomized 301 patients who had been diagnosed with and were receiving treatment for anterior AMI with either PCI plus the SSO_2 Therapy or PCI alone.[65] The AMIHOT II trial had a Bayesian statistical design that allows for the informed borrowing of data from the previously completed AMIHOT I trial. The primary efficacy endpoint of the study required proving superiority of the infarct size reduction, as assessed by Tc-99m Sestamibi SPECT imaging at 14 days post PCI/stenting, with the use of SSO_2 Therapy as compared to patients who were receiving treatment involving PCI with stenting alone. The primary safety endpoint for the AMIHOT II trial required a determination of non-inferiority in the 30-day MACE rate, comparing the SSO_2 Therapy group with the control group, within a safety delta of 6.0 percent.[66] Endpoint evaluation was performed using a Bayesian hierarchical model that evaluated the AMIHOT II result conditionally in consideration of the AMIHOT I 30-day MACE data. According to the applicant, the results of the AMIHOT II trial showed that the use of SSO_2 therapy, together with PCI and stenting, demonstrated a relative reduction of 26 percent in the left ventricular infarct size and absolute reduction of 6.5 percent compared to PCI and stenting alone.[67]

Next, to support the claim that SSO_2 Therapy prevents left ventricular dilation, the applicant cited the Leiden study, which represents a single-center, sub-study of AMIHOT I patients treated at Leiden University in the Netherlands. The study describes outcomes of randomized selective treatment with intracoronary aqueous oxygen (AO), the therapy delivered by SSO_2 Therapy, versus standard care in patients who had acute anterior wall myocardial infarction within 6 hours of onset. Of the 50 patients in the sub-study, 24 received treatment using adjunctive AO and 26 were treated according to standard care after PCI, with no significant differences in baseline characteristics between groups. LV volumes and function were assessed by contrast echocardiography at baseline and 1 month. According to the applicant, the results demonstrated that treatment with aqueous oxygen prevents LV remodeling, showing a reduction in LV volumes (3 percent decrease in LV end-diastolic volume and 11 percent decrease in LV end-systolic volume) at 1 month as compared to baseline in AO-treated patients, as compared to increasing LV volumes (14 percent increase in LV end diastolic volume and 18 percent increase in LV end-systolic volume) at 1 month in control patients.[68] The results also show that treatment using AO preserves LV ejection fraction at 1 month, with AO-treated patients experiencing a 10 percent increase in LV ejection fraction as compared to a 2 percent decrease in LV ejection fraction among patients in the control group.[69]

Finally, to support the claim that SSO_2 Therapy reduces death and heart failure at 1 year, the applicant submitted the results from the IC–HOT clinical trial, which was designed to confirm the safety and efficacy of the use of the SSO_2 Therapy in those individuals presenting with a diagnosis of anterior AMI, who have undergone successful PCI with stenting of the proximal and/or mid left anterior descending artery within 6 hours of experiencing AMI symptoms. It is an IDE, nonrandomized, single arm study. The study primarily focused on safety, utilizing a composite endpoint of 30-day Net Adverse Clinical Events (NACE). A maximum observed event rate of 10.7 percent was established based on a contemporary PCI trial of comparable patients who had been diagnosed with anterior wall STEMI. The results of the IC–HOT trial exhibited a 7.1 percent observed NACE rate, meeting the study endpoint. Notably, no 30-day mortalities were observed, and the type and frequency of 30-day adverse events occurred at similar or lower rates than in contemporary STEMI studies of PCI-treated patients who had been diagnosed with anterior AMI.[70] Furthermore, according to the applicant, the results of the IC–HOT study supported the conclusions of effectiveness established in AMIHOT II with a measured 30-day median infarct size = 19.4 percent (as compared to the AMIHOT II SSO_2 Therapy group infarct size = 20.0 percent).[71] The applicant stated that notable measures include 4-day microvascular obstruction (MVO), which has been shown to be an independent predictor of outcomes, 4-day and 30-day left ventricular end diastolic and end systolic volumes, and

[62] O'Neill, W.W., Martin, J.L., Dixon, S.R., et al., ''Acute Myocardial Infarction with Hyperoxemic Therapy (AMIHOT), *J Am Coll Cardiol,* 2007, vol. 50(5), pp. 397–405.

[63] Ibid.

[64] Ibid.

[65] Stone, G.W., Martin, J.L., de Boer, M.J., et al., ''Effect of Supersaturated Oxygen Delivery on Infarct Size after Percutaneous Coronary Intervention in Acute Myocardial Infarction,'' *Circ Cardiovasc Intervent,* 2009, vol. 2, pp. 366–75.

[66] Ibid.

[67] Ibid.

[68] Warda, H.M., Bax, J.J., Bosch, J.G., et al., ''Effect of intracoronary aqueous oxygen on left ventricular remodeling after anterior wall ST-elevation acute myocardial infarction,'' *Am J Cardiol,* 2005, vol. 96(1), pp. 22–4.

[69] Ibid.

[70] David, SW, Khan, Z.A., Patel, N.C., et al., ''Evaluation of intracoronary hyperoxemic oxygen therapy in acute anterior myocardial infarction: The IC–HOT study,'' *Catheter Cardiovasc Interv,* 2018, pp. 1–9.

[71] Ibid.

30-day infarct size.[72] The applicant also stated that the IC–HOT study results exhibited a favorable MVO as compared to contemporary trial data, and decreasing left ventricular volumes at 30 days, compared to contemporary PCI populations that exhibit increasing left ventricular size.[73] The applicant asserted that the IC–HOT clinical trial data continue to demonstrate the substantial clinical benefit of the use of SSO_2 Therapy as compared to SOC, PCI with stenting alone.

The applicant also performed controlled studies in both porcine and canine AMI models to determine the safety, effectiveness, and mechanism of action of the SSO_2 Therapy.[74] [75] According to the applicant, the key summary points from these animal studies are:

- SSO_2 Therapy administration post-AMI acutely improves heart function as measured by left ventricular ejection fraction (LVEF) and regional wall motion as compared with non-treated control subjects.
- SSO_2 Therapy administration post-AMI results in tissue salvage, as determined by post-sacrifice histological measurements of the infarct size. Control animals exhibit larger infarcts than the SSO_2-treated animals.
- SSO_2 Therapy has been shown to be non-toxic to the coronary arteries, myocardium, and end organs in randomized, controlled swine studies with or without induced acute myocardial infarction.
- SSO_2 Therapy administration post-AMI has exhibited regional myocardial blood flow improvement in treated animals as compared to controls.
- A significant reduction in myeloperoxidase (MPO) levels in the SSO_2-treated animals versus controls, which indicate improvement in underlying myocardial hypoxia.
- Transmission electron microscopy (TEM) photographs showing amelioration of endothelial cell edema and restoration of capillary patency in ischemic zone cross-sectional histological examination of the SSO_2-treated animals, while non-treated controls exhibit significant edema and vessel constriction at the microvascular level.

In the FY 2020 final rule (84 FR 42278), after consideration of all the information from the applicant, as well as the public comments we received, we stated that we were unable to determine that SSO_2 Therapy represented a substantial clinical improvement over the currently available therapies used to treat STEMI patients. We stated that we remained concerned that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represented a substantial clinical improvement over existing available options. Therefore, we did not approve new technology add-on payments for SSO_2 Therapy for FY 2020.

For FY 2021, the applicant submitted new information that, according to the applicant, demonstrates that there is an unmet medical need for STEMI, and that SSO_2 Therapy provides a treatment option for a patient population unresponsive to currently available treatments. The applicant presented this information in the context of CMS's concerns as identified in the FY 2020 IPPS/LTCH PPS proposed and final rules, specifically that (1) it is unclear whether use of the SSO_2 Therapy would demonstrate the same clinical improvement as compared to the current standard of care; (2) that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy, and (3) that SSO_2 may not provide long-term clinical benefits in patients with AMI. Below we summarize this information, which the applicant believes addresses these concerns.

With regard to CMS's concern that it is unclear whether use of SSO_2 Therapy would demonstrate the same clinical improvement as compared to the current standard-of care, the applicant restated our concern as whether ''these data [AMIHOT I and AMIHOT II are] adequate to show the relevant outcomes in the control (standard of care percutaneous coronary intervention (PCI))''. In response to this concern, the applicant asserted that patient outcomes post-PCI have remained relatively stable over the past 10 years and there is a strong clinical need for new therapies like SSO_2 in addition to PCI in the management of patients with anterior STEMI to reduce the risk and severity of heart failure and death. To support its assertion of an unmet clinical need for anterior wall STEMI treatment, the applicant presented data from multiple references to illustrate the following:

- A plateau in STEMI 1-year mortality rates at 10 percent with the advent of drug-eluting stents, according to reports from the SWEDEHEART registry. This statistic is in agreement with the 9% 1 year STEMI mortality rate following PCI reported in a 2015 paper by Bullock et al.[76]
- No improvement in U.S. in-hospital post-PCI STEMI mortality rates between 2001 and 2011 based on work done by Sugiyama et al.[77]
- No decrease in one-year mortality risk as illustrated by Kalesan et al.,[78] a meta-analysis of 15 clinical trials totaling 7,867 patients that compared outcomes data for STEMI patients treated with bare metal stents versus drug eluting stents.[79]
- A markedly higher one-year mortality rate at 19.4% for the Medicare population as compared to the total population of PCI-treated anterior wall STEMI patients, according to the most recent Medicare Standard Analytic File (SAF) data (2017).
- No improvement in congestive heart failure (CHF) rates after STEMI treated pPCI; the applicant referenced Szummer et al.'s [80] work which indicated 1 year post primary PCI CHF rates of 10 percent as well as a statistical analysis of CHF readmission outcomes that showed heart failure rates for this patient population have remained stable at 9 to 10 percent from 2012 to 2017.
- A decrease in 30-day STEMI re-hospitalizations due to the evolution of PCI therapy; the applicant cited the work of Kim et al.,[81] noting the readmission rates trended slightly downward from approximately 12 percent in 2010 to 10 percent in 2014. According to the applicant, these data

[72] Ibid.

[73] Ibid.

[74] Spears, J.R., Henney, C., Prcevski, P., et al., ''Aqueous Oxygen Hyperbaric Reperfusion in a Porcine Model of Myocardial Infarction,'' *J Invasive Cardiol,* 2002, vol. 14(4), pp. 160–6.

[75] Spears, J.R., Prcevski, P., Xu, R., et al., ''Aqueous Oxygen Attenuation of Reperfusion Microvascular Ischemia in a Canine Model of Myocardial Infarction,'' *ASAIO J,* 2003, vol. 49(6), pp. 716–20.

[76] Bulluck H, Yellon DM, and Hausenloy DJ. Reducing myocardial infarct size: Challenges and future opportunities. Heart 2016;102:341–48.

[77] Sugiyama T, Hasegawa K, Kobayashi Y, Takahashi O, Fukui T, Tsugawa Y. Differential time trends of outcomes and costs of care for acute myocardial infarction hospitalizations by ST elevation and type of intervention in the United States, 2001–2011. J AmHeart Assoc. 2015;4:e001445. doi:10.1161/JAHA.114.001445.

[78] Kalesan B, Pilgrim T, Heinimann K, et al. Comparison of drug-eluting stents with bare metal stents in patients with ST-segment elevation myocardial infarction. Eur Heart J 2012;33:977–87.

[79] Id.

[80] Szummer K, Wallentin L, Lindhagen L, et al. Improved outcomes in patients with ST-elevation myocardial infarction during the last 20 years are related to implementation of evidence-based treatments: experiences from the SWEDEHEART registry 1995–2014. Eur Heart J 2017;38:3056–65.

[81] Kim LK, Yeo I, Cheung, JW, et al. Thirty-Day Readmission Rates, Timing, Causes, and Costs after ST-Segment Myocardial Infarction in the United States: A National Readmission Database Analysis 2010–2014. J Am Heart Assoc 2018;7(18):1–34.

illustrate that PCI treats macrovascular aspects of STEMI events, but does not address the underlying infarct damage, which is highly correlated with worse long-term outcomes.

The applicant reiterated statements from its prior application that, in order to reduce outcomes like mortality and heart failure in the STEMI population, therapies must be available above and beyond PCI to reduce the size of the infarct that results from a STEMI event. Per the applicant, the benefits shown in the AMIHOT I 6-hour sub-study, AMIHOT II and IC–HOT studies show statistically significant and clinically meaningful improvements in infarct size, left ventricular size and function, and long term outcomes that support the claim that SSO_2 offers a substantial clinical improvement over PCI by filling an important gap in therapy with PCI, and specifically the need to reduce infarct size beyond simply opening occluded large vessels alone.

With regard to CMS's second concern that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy, the applicant restated our concern as ''the importance of the reduction of infarct size as an outcome for patients with anterior STEMI.'' The applicant provided multiple animal and human studies to illustrate how TherOx SSO_2 potentially impacts outcome measures of heart failure, rehospitalization and mortality. Regarding animal studies, the applicant cited the porcine and canine study by Spears et al. and summarized above to illustrate how aqueous oxygen hyperoxemic perfusion attenuates microvascular ischemia.[82] [83] Regarding human studies, the applicant cited a 2004 review by Gibbons et al. to support its assertion that the best physical measure of the consequences of AMI in post-intervention patients is the quantification of the extent of necrosis or infarction in the muscle. In this 2004 review article, Gibbons et al. sought to summarize published evidence for quantification of infarct size using data from studies that assessed biomarkers, cardiac SPECT sestamibi and magnetic resonance imaging.[84] Regarding the use of cardiac SPECT sestamibi imaging, Gibbons et al. found five separate lines of clinical evidence that validated the use of SPECT sestamibi imaging for determining infarct size.[85] The applicant also referenced the CORE trial that it submitted with its original application and which we summarize above. Per the applicant, a substudy of CORE trial data by Burns et al. demonstrated that an absolute infarct size reduction of 3 percent was associated with a mortality benefit.[86] Specifically, the trial showed that six-month mortality was significantly related to infarct size. Per the applicant, among the 753 patients who underwent ejection fraction measurements, the odds ratio for infarct size for six-month mortality was 1.033—that is, for each 1 percent increase in infarct size, mortality in the next 6 months was 1.033 times more likely. A 5 percent increase in infarct size would therefore mean that 6-month mortality was 1.176 times more likely. A patient with an infarct size that was greater by 5 percent of the left ventricle would therefore have a 17.6 percent greater chance of dying within the next 6 months.[87]

The applicant further noted the CORE trial and associated studies were conducted when thrombolytic therapy was the standard of care for coronary artery reperfusion. The transition to PCI led directly to a measured absolute infarct size reduction of 5.1 percent in STEMI patients treated with PCI as compared to thrombolytic therapy, which correlated to a significant decrease in cardiovascular events. The applicant asserted that the infarct size reduction demonstrated with PCI compared to thrombolytic therapy helped establish PCI as the preferred standard of care, and that the results demonstrating the importance of infarct size reduction hold true in randomized PCI trials of STEMI patients, with infarct size evaluated by either Tc-99 sestabmibi SPECT imaging or cardiac MRI. The applicant referred to the substudy of CORE trial data by Burns et al., which found that, among the three clinical prognostic outcomes studied, ejection fraction (EF) was superior to infarct size (IS) and end-systolic volume index (ESVI) in predicting 6-month mortality.[88] The authors also noted that all three radionuclide measures were significantly associated with each other, and that the strongest correlation was between ESVI and EF. The study noted that infarct size was significantly correlated with both EF and ESVI despite being determined from a different radionuclide measurement, and that infarct location was not found to be significant.[89]

The applicant also provided a study by Stone et al.[90] to address our concern that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy. The applicant provided Stone et al.'s recent analysis of 10 pooled randomized trials involving 2,632 subjects, including some subjects from the AMIHOT II trial. Stone et al. set out to determine the strength of the relationship between infarct size assessed within 1 month after pPCI in STEMI and subsequent all-cause mortality, reinfarction and hospitalization for heart failure.[91] Infarct size was assessed using cardiac SPECT sestamibi or cardiac magnetic resonance and clinical follow-up data greater than or equal to 6 months. The authors found infarct size reduction measured by either imaging method within 1 month correlated strongly with reduced mortality and heart failure hospitalization at 1 year. The applicant asserted that the results demonstrated that every 5 percent absolute increase in left ventricular infarct size was associated with a 19 percent increase in 1-year mortality, correlating well with the 17.6 percent estimate established from earlier data and underscoring the important, independent relationship between infarct size and mortality regardless of the treatment modality. The applicant asserted that the published analysis also demonstrated that infarct size measured within 1 month after pPCI for STEMI using either imaging method is a powerful independent predictor of hospitalization for heart failure at 1 year. The applicant reiterated that overall, a 5 percent absolute infarct size increase was associated with a 20 percent increase in either death or heart failure at 1 year. The applicant explained that because infarct size is the quantification of the extent of scarring of the left ventricle post-AMI, it is a direct measure of the health of the myocardium and indirectly of the heart's structure and function. A

[82] Spears JR, Henney C, Prcevski P, et al. Aqueous Oxygen Hyperbaric Reperfusion in a Porcine Model of Myocardial Infarction. *J Invasive Cardiol* 2002; 14(4):160–6.

[83] Spears JR, Prcevski P, Xu R, et al. Aqueous Oxygen Attenuation of Reperfusion Microvascular Ischemia in a Canine Model of Myocardial Infarction. *ASAIO J* 2003; 49(6):716–20.

[84] Gibbons RJ, Valeti US, Araoz PA, et al. The quantification of infarct size. *J Am Coll Cardiol* 2004; 44:1533–42.

[85] Id.

[86] Burns RJ, Gibbons RJ, Yi Q, et al. The relationships of left ventricular ejection fraction, end-systolic volume index and infarct size to six-month mortality after hospital discharge following myocardial infarction treated by thrombolysis. *J Am Coll Cardiol* 2002; 39:30–6.

[87] Id.

[88] Id.

[89] Id.

[90] Stone GW, Selker, HP, Thiele H, et al. Relationship between infarct size and outcomes following primary PCI. JACC 2016;67(14):1674–83.

[91] Id.

large infarct means the muscle cannot contract normally, leading to left ventricular enlargement, reduced ejection fraction, clinical heart failure, and death. Per the applicant, the Kaplan-Meier curves for the rates of heart failure at 12 months as a function of infarct size also show that a 5 percent increase in left ventricle infarct size corresponded to a 50–100 percent increase in the risk of heart failure at 12 months for the most severe infarcts. The applicant concluded that reducing infarct size 5 or more percentage points provides a clear and dramatic clinical benefit for patients as demonstrated by a wealth of trial data. Significantly, the applicant noted that even as treatment of the primary occlusion improved, the relationship between infarct size and mortality and heart failure persisted and remained present throughout the study data.

Finally, with regard to CMS's third concern that SSO_2 may not provide long-term clinical benefits in patients with AMI, the applicant again referred to the 1-year outcomes data collected from patients in the IC–HOT trial and which were compared to a control population from the INFUSE AMI study after propensity-matching. The applicant asserted that STEMI patients treated with SSO_2 Therapy showed statistically significant and clinically meaningful improvements in several critically important outcomes for patients with anterior STEMI at 1 year, such as—

- Death;
- New onset of heart failure and readmission for heart failure;
- Composite rate of death and new onset of heart failure;
- Composite rate of death, new onset of heart failure or readmission for heart failure, or clinically-driven target vessel revascularization;
- Composite of death, reinfarction/spontaneous MI, clinically driven target vessel revascularization or new onset heart failure or readmission for heart failure.

The applicant concluded that, taken together, there is abundant evidence to support the claim that SSO_2 Therapy represents a substantial clinical improvement over PCI alone in the management of patients with anterior STEMI. Per the applicant, there remains a strong unmet need for new therapies like SSO_2 in addition to PCI in the management of patients with anterior STEMI to reduce the risk and severity of heart failure and death. The applicant maintained that the timely delivery of supersaturated oxygen therapy improves microvascular and tissue level flow, reduces infarct size, facilitates recovery of left ventricular function and preserves left ventricular stability, and improves patient outcomes, most notably lowering mortality and heart failure rates at 1 year post-procedure.

We thank the applicant for the additional information to address the concerns discussed in the FY 2020 IPPS/LTCH PPS final rule. We appreciate how this information, and specifically the seven studies referenced in response to the applicant's restatement of our first concern, illustrates a potential unmet medical need. However, we stated in the proposed rule that we are concerned that the AMIHOT I and AMIHOT II data may not adequately demonstrate the relevant outcomes in the control (standard of care PCI) because the standard of care has evolved since the two trials were performed. Additionally, we stated that we are concerned that the results presented in these seven studies may be based on patients with all types of STEMI and are not specific to the FDA-approved indicated use of SSO_2 Therapy for the treatment of anterior STEMI. We stated that ultimately, we remain concerned that the current data does not support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represents a substantial clinical improvement over existing available options. Therefore, we invited public comment on whether SSO_2 Therapy meets the substantial clinical improvement criterion.

We invited public comments on whether the SSO_2 Therapy meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments regarding the concerns raised by CMS in the proposed rule about whether SSO_2 Therapy meets the substantial clinical improvement criterion. The commenter first recapped the clinical studies used to support SSO_2 Therapy's Premarket Approval, which were the AMIHOT I and II and IC–HOT clinical trials.

As discussed in the FY 2020 IPPS/LTCH PPS final rule and the FY 2021 IPPS/LTCH PPS proposed rule, the AMIHOT I was a prospective, randomized study that enrolled both inferior and anterior STEMI patients assigned to either PCI with stenting alone (control group) or with SSO_2 administered post-PCI (treatment group). The AMIHOT I trial showed a therapeutic benefit in the pre-specified anterior STEMI subgroup by reducing infarct size (the primary endpoint). However, as the AMIHOT I was not designed to test statistical superiority in the subgroup with anterior STEMI, for which SSO_2 Therapy is indicated, the manufacturer undertook a second prospective, randomized controlled trial for this population, the AMIHOT II study.

The AMIHOT II trial only enrolled anterior STEMI patients randomized to either PCI with stenting alone (control) or with SSO_2 administered post-PCI (treatment). At the FDA's recommendation, the AMIHOT II utilized a pre-specified Bayesian statistical model for the primary endpoint analysis, which pooled anterior STEMI patients from the AMIHOT I and AMIHOT II patients. The results of AMIHOT II demonstrated superiority in the anterior STEMI population for the primary endpoint of reducing infarct size, or heart muscle damage, which the commenter asserted is a well-recognized predictor of heart failure and mortality.[92]

Finally, the manufacturer undertook a third study, IC–HOT.[93] The purpose of IC–HOT was to confirm the safety and efficacy results of SSO_2 Therapy after technical modifications to device design. Per the applicant, the IC–HOT study enrolled a treatment-only cohort, met its primary endpoint, and confirmed the earlier AMIHOT findings for infarct size reduction and mortality. The commenter noted that the results are consistent across all key studies and demonstrate that SSO_2 Therapy significantly reduces infarct size, or heart muscle damage.

Next, the applicant presented two new studies that had not been available at the time its FY 2021 new technology add-on payment application was submitted. The first (which the applicant referred to as the Chen paper) was an analysis of mortality and heart failure rates found in IC–HOT patients as compared to a historical propensity-matched population of anterior STEMI patients from the 2012 INFUSE–AMI trial. The applicant referenced this analysis in its FY 2021 new technology add-on payment application and has since had it peer-reviewed and accepted for publication. The analysis presented one-year follow-up data showing mortality and heart failure rates between the two groups. This new data showed treatment with SSO_2 Therapy was associated with a lower 1-year rate of

[92] Stone GW, Selker, HP, Thiele H, et al. Relationship between infarct size and outcomes following primary PCI. *J Am Coll Cardiol* 2016;67(14):1674–83.

[93] David SW et al. Evaluation of intracoronary hyperoxemic oxygen therapy in acute anterior myocardial infarction: The IC–HOT study. *Catheter Cardiovasc Interv, 2019:93*(5);882–90.

the composite endpoint of all-cause death or new-onset heart failure or hospitalization for heart failure (0.0% vs. 12.3%, p=0.001), with reductions in the individual 1-year outcomes of death (0% vs. 7.6%, p=0.01) and new-onset heart failure or hospitalization for heart failure (0.0% vs. 7.4%, p =0.001). However, we note that the applicant did not observe a statistically significant result in the outcome measurements of reinfarction and target vessel revascularization.

The applicant also commissioned the Medicare Mortality Analysis, which matched the IC–HOT patients with a population of anterior STEMI patients from 2018 Medicare inpatient data. The populations were matched for multiple covariates, using propensity scores and regression analysis. The applicant applied the same inclusion and exclusion criteria as the IC–HOT study, resulting in an eligible comparison group of 2,587 cases. The applicant then developed one-year follow-up data showing mortality rates between the two groups. Per the applicant, the IC–HOT treatment group had no mortality over the 30-day and 1-year follow-up periods, in contrast to the matched Medicare comparison group, which had a 30-day mortality of 5 percent and a 1-year mortality of 7.3 percent. The applicant stated that the differences in mortality between the IC–HOT sample and the matched Medicare sample were statistically significant at a 5 percent significance level. The applicant further developed data showing differences in the rate of re-hospitalization for chronic heart failure. The applicant found that the mortality rate in the IC–HOT sample was 1 percent over the 30-day and 1-year follow-up periods, but that the difference between the two populations was not statistically significant.

The applicant also presented a Medicare Longitudinal Analysis of heart failure outcomes in anterior STEMI patients treated with PCI. The applicant obtained Medicare inpatient claims data from 2005–2008 (when the AMIHOT trials were conducted) and from 2016–2018 (during enrollment of the IC–HOT trial). Because the 2005–2007 Medicare Inpatient Limited Datasets only report the quarter of discharge from the hospital, the applicant examined outcomes by quarters and divided their sample into two cohorts based on year of discharge from the hospital. The early cohort included cases discharged in 2005 and 2007, and the later cohort included cases discharged in 2016, 2017, and 2018. The applicant found that, among Medicare beneficiaries diagnosed with STEMI who are treated with PCI with stenting, 4-quarter mortality rates following hospitalization was 8.9 percent in the 2005/2007 cohort and 10.3 percent in the 2016/2017/2018 cohort. While the difference in these mortality rates between the early and later cohorts was statistically insignificant, the 8-quarter mortality rate increased from 11.4 percent in 2005 to 14.5 percent in 2016/2017, yielding a statistically significant difference of 3.1 percentage points. Per the applicant, controlling for differences in clinical characteristics between the early and later cohorts using Elixhauser comorbidities yielded a 4 quarter mortality rate that increased by 2.3 percentage points, and an 8-quarter mortality rate that increased by 4.2 percentage points between early and later cohorts. Per the applicant, risk-adjusted 4-quarter rehospitalization rates for chronic heart failure decreased by 6.9 percentage points between the 2005/2007 cohort and the 2016/2017/2018 cohort. The applicant found no statistically significant change in 8-quarter rehospitalization rate for chronic heart failure between the two cohorts. Per the applicant, these results demonstrate that mortality and heart failure outcomes in anterior STEMI patients treated with PCI have not improved since 2005 between the matched population of the earlier cohort and the later cohort.

The applicant then addressed CMS' concerns (85 FR 32613) individually. With respect to the concern that the AMIHOT I and AMIHOT II data may not adequately demonstrate the relevant outcomes in the control group because the standard of care has evolved since the two trials were performed, the applicant responded that refinements to the standard of care have not improved mortality or heart failure since the studies were conducted. According to the applicant, the changes to the standard of care since AMIHOT I and AMIHOT II were conducted have been modest rather than transformative, and largely comprised of (1) earlier PCI intervention through reduced door-to-balloon times, (2) new adjunctive pharmacological alternatives, and (3) incremental improvements in stent design and delivery tools and techniques. The applicant reiterated that these changes have led to a reduction in rehospitalization and revascularization, but no improvement in mortality or heart failure rates.

The applicant further noted that, with respect to earlier PCI intervention, it is important to recognize that door-to-balloon times in the AMIHOT control groups were already at the optimized levels seen in clinical practice today, as evidenced by the requirement in the AMIHOT trials to perform successful PCI within 6 hours of symptom onset, and the adherence to prompt door-to-balloon times in the PCI centers that participated in the study.[94] Accordingly, the applicant asserted that the AMIHOT control group accurately reflects the current standard of care in this manner. The applicant asserted that other refinements have resulted in better PCI results, but have not improved mortality or heart failure rates. For example, the migration from bare metal stents to drug-eluting stents reduced target vessel revascularization rate by 46% but did not reduce cardiac death.[95] The applicant referenced the Medicare Longitudinal Analysis, which saw an increase in the one-year mortality rate from 7.8% in 2005 to 10.8% in 2018. The applicant noted that, in the same analysis, the trend in two-year mortality rate also increased from 11.4% in 2005 to 15.3% in 2017. Similarly, two-year heart failure rate increased from 7.8% in 2005 to 10.6% in 2018.

The applicant concluded that both the clinical literature and Medicare's own anterior STEMI patient data demonstrate refinements to the PCI standard of care have not resulted in improved heart failure or mortality for anterior STEMI patients since the conduct of the AMIHOT trials, and that the AMIHOT I and II control group continues to be relevant. The applicant reiterated that, without a therapy to address microvascular injury in the heart muscle following an anterior STEMI, outcomes that are strongly correlated to microvascular injury are unlikely to improve. The applicant stated that in contrast to PCI refinements, SSO_2 Therapy is specifically designed to address microvascular injury and improves anterior STEMI outcomes related to the development of heart failure and heart failure mortality.

With respect to the concern that the results presented in the seven studies submitted with the applicant's FY 2021 application were based on patients with all types of STEMI and are not specific to the FDA-approved indicated use of SSO_2 Therapy for the treatment of anterior STEMI, the applicant responded that the studies presented are relevant even though they were not specific to the FDA approved indication. The applicant stated that the AMIHOT II and IC–HOT studies targeted the anterior STEMI population

[94] Median D2B = 75 min for Controls and 77 min for SSO_2 subjects in the AMIHOT II trial.

[95] Kalesan et. al. Comparison of drug-eluting stents with bare metal stents in patients with ST-segment elevation myocardial infarction. *Euro Heart J* 2012;33:977–87.

after the pre-defined anterior STEMI subgroup in AMIHOT I saw the greatest benefit from SSO_2 Therapy. To further confirm these results, the applicant referenced the Medicare Mortality Analysis, which included only anterior STEMI patients. The new analysis showed that the IC–HOT treatment group had no mortality over 30-day and 1-year follow-up periods. In contrast, the propensity-matched population from 2018 Medicare inpatient data had a 30-day mortality of 5 percent, and 1-year mortality of 7.3 percent. The differences in mortality between the IC–HOT sample and the matched Medicare sample were statistically significant at a 5 percent significance level, while the differences in re-hospitalization rate for CHF between the IC–HOT sample and the matched Medicare sample were statistically insignificant.

The applicant noted that its FY 2021 application included a wide array of data demonstrating the absence of progress in mortality or heart failure outcomes in all types of STEMI patients, since large, longitudinal STEMI studies reported by infarct location are limited. As seen in AMIHOT I and the Medicare Mortality Analysis, clinical outcomes are worse in anterior STEMI patients and this population drives overall STEMI mortality and heart failure rates. The applicant again referenced the Medicare Longitudinal Analysis, which is derived from CMS data and specific to the anterior STEMI and matched population to support their assertion that there is a lack of progress in improving mortality and heart failure outcomes in anterior STEMI patients between 2005 and 2018. The applicant explained that anterior STEMI carries a higher heart failure and mortality risk and thus any data presented that is not specific to the anterior STEMI population would tend to cause a bias towards underestimating adverse outcomes with anterior STEMI and therefore underestimate the clinical benefit from SSO_2 Therapy by comparison.[96] The applicant maintained that all clinical data reported showing a benefit of SSO_2 Therapy are among patients with anterior STEMI, so this bias can only exist for comparison data. The applicant stated as such, comparisons of SSO_2 Therapy data in patients with anterior STEMI to data among patients with STEMI overall would tend to understate the benefits of SSO_2 Therapy.

With respect to CMS' third concern that the current data does not support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represents a substantial clinical improvement over existing available options, the applicant submitted new supporting analyses while disagreeing with CMS' assessment. The applicant submitted the newly published Chen Paper which compares the outcomes of the most recent trial data from IC–HOT to an appropriate comparator population of subjects receiving the standard of care. As noted above, results demonstrated clinically and statistically lower one-year rates of mortality and heart failure in anterior STEMI patients treated with SSO_2 Therapy as compared to a propensity matched population treated with only PCI. Per the applicant, the Medicare Mortality Analysis replicated these findings and demonstrated a clinically and statistically significant one-year mortality reduction in anterior STEMI patients treated with SSO_2 Therapy as compared to matched control patients treated with only PCI.

Finally, the applicant also compared outcomes of this same matched IC–HOT population to outcomes from the PCI standard of care control group from the CONDI–2/ERIC PPCI study, which to the commenter's knowledge is the most recently reported study with a large PCI control group.[97] Per the applicant, this trial included 974 anterior STEMI control patients with outcomes very similar to those presented from the matched INFUSE–AMI population. The applicant stated that the one-year mortality and heart failure rates for the anterior STEMI patients analyzed were 5.2% and 11.6%, respectively. The applicant noted that these outcomes are consistent with the matched control populations above and substantially worse than the IC–HOT SSO_2-treated group.

The applicant reiterated that, as seen in the AMIHOT I, AMIHOT II, and IC–HOT trials, SSO_2 Therapy reduces infarct size. The applicant asserted that preserving heart tissue and reducing infarct size in patients who have had an anterior STEMI leads to heart function improvement, and patients experience fewer heart failure episodes, fewer heart failure symptoms, and lower incidence of death. The applicant maintained that this is a substantial clinical improvement beyond standard anterior STEMI care, not only because infarct size is itself clinically important, but also because, per the applicant, research has shown that use of SSO_2 Therapy reduces rates of death and heart failure in the intended use population. The applicant asserted that, consistently, across multiple control groups, large and small, randomized and matched, SSO_2 Therapy outperformed PCI alone in the critical outcomes of mortality and heart failure. The applicant further asserted that these results support the benefit of employing a treatment strategy of effective PCI first, then healing the injured myocardium with SSO_2 Therapy administration.

In conclusion, the commenter stated that the data presented in the FY2021 new technology add-on payment application supplemented by the data presented in its comment letter show that SSO_2 Therapy meets the substantial clinical improvement criterion in addition to meeting the newness and cost criteria and merits approval for new technology add-on payments for FY 2021. The commenter stated that denial of new technology add-on payments would limit use of this beneficial technology in many hospitals, and disproportionately hinder improvements in anterior STEMI outcomes in economically disadvantaged communities, including rural areas, and prolong treatment for critical care.

We also received comments from several other commenters asserting that SSO_2 Therapy filled an unmet medical need while also being superior to the current standard of care, PCI with stenting. These commenters stated that there have been no significant advancements in anterior STEMI treatment that have impacted infarct size or heart failure since the AMIHOT I and AMIHOT II trials were conducted. According to these commenters, other drugs and therapies have not been able to reduce infarct size and had limited impact on reducing death and heart failure hospitalization rates. Additionally, several commenters reviewed the clinical data from the AMIHOT I, AMIHOT II, and IC–HOT trials for reductions in infarct size and improved ejection fraction and other indications of improved patient outcomes, which they believe correlate to reduced heart failure and improved mortality beyond the benefit of PCI and stenting alone.

Several commenters cited their personal experience treating patients with SSO_2 Therapy and noted the positive results in these patients,

[96] Entezarjou et al. Culprit vessel: Impact on short-term and long-term prognosis in patients with ST-elevation myocardial infarction. *Open Heart* 2018;5:e000852. doi:10.1136/openhrt–2018–000852.

[97] Hausenloy DJ et al. Effect of remote ischaemic conditioning on clinical outcomes in patients with acute myocardial infarction (CONDI–2/ERIC–PPCI): a single-blind randomized controlled trial. *Lancet* 2019; 394: 1415–24.

including signs of clinical recovery such as restored normal heart functions and improved ejection fraction that they believe would not have occurred under PCI with stenting alone. One such commenter claimed to have treated three patients who all showed normal heart functions within one month of being treated with SSO_2 Therapy. Overall, these commenters expressed their support of the applicant's claim that SSO_2 Therapy has a measurable improved impact on patient outcomes and quality of life measurements.

Response: We appreciate the commenters' input, including the additional information and analysis submitted by the applicant to address CMS' concerns. With respect to the original studies, we note that the AMIHOT I was a Phase II study designed to test efficacy. We also note that, while AMIHOT I and AMIHOT II were randomized, they were designed to show that SSO_2 Therapy reduces infarct size but were not designed to demonstrate improved outcomes among anterior STEMI patients.

The IC–HOT study was a single-arm study that recruited a treatment-only group to confirm an objective safety performance goal, and was not statistically powered to look at any efficacy endpoint. The applicant compared one-year clinical outcomes to a propensity-matched control group of similar patients with anterior STEMI enrolled in the INFUSE–AMI trial. We recognize that the results show all-cause mortality, driven by cardiovascular mortality, and new-onset heart failure or heart failure hospitalization, were each individually lower in patients treated with SSO_2 Therapy. However, there may be variability from the types of patients enrolled in a single-arm registry such as IC–HOT and those in a comparator control group drawn from the randomized INFUSE–AMI trial. We note that the IC–HOT trial included more patients in Killip Class I (individuals with no clinical signs of heart failure), with 95.2 percent of patients compared to 85.5 percent of patients enrolled in INFUSE–AMI. We also note that IC–HOT had fewer patients in Killip Class II (individuals with rales or crackles in the lungs, an S_3, and elevated jugular venous pressure), with 3.6 percent of patients compared to 13.2 percent in INFUSE–AMI.

As stated by the applicant and summarized above, the Chen paper was an analysis of mortality and heart failure rates found in IC–HOT patients as compared to a propensity-matched population enrolled in the INFUSE–AMI trial. Chen et al. noted the following study limitations: (1) The population represents a selected cohort of patients and, therefore, its findings may not apply to all patients with STEMI, such as those with cardiogenic shock, nonanterior MI, and others who did not undergo pPCI with stenting within six hours of symptom onset; (2) because patients from the comparator control group were drawn from the randomized INFUSE–AMI trial, there may be variability from the types of patients enrolled in a single-arm registry such as IC–HOT; and (3) they could not rule out the possibility that its analysis was confounded by other unmeasured factors that are correlated with SSO_2 Therapy treatment. Chen et al. concluded that based on the overall review of the data and study limitations that its results should be considered only hypothesis-generating. Finally, Chen et al. noted that the study results were an analysis from a modest-sized propensity-matched cohort and recommended appropriately powered randomized controlled trials to demonstrate the effect of SSO_2 Therapy treatment on outcomes in patients with anterior STEMI after successful PCI.

We also reviewed two additional studies the applicant submitted, the Medicare Mortality Analysis and the Medicare Longitudinal Analysis. Per the applicant, these studies show that there is an unmet medical need in the population of anterior STEMI patients, as well as the superiority of SSO_2 Therapy over PCI with stenting alone in mortality and heart failure outcomes among anterior STEMI patients. However, these analyses used results from the IC–HOT study, a study designed to look at safety only, to reach an efficacy endpoint. Similarly, though they state that the design of the Medicare Mortality Analysis used a propensity-matched population of anterior STEMI patients from Medicare inpatient data, and the Medicare Longitudinal Analysis also used matching to ensure appropriate comparison populations, it is unclear if baseline morbidity and other confounding factors were matched between arms.

We also note that the FDA ordered a post-approval study to confirm the safety and effectiveness of SSO_2 Therapy. The FDA specified that the new enrollment study should be a prospective global, multicenter, randomized (1:1), confirmatory study with patients randomized to either standard therapy or post-procedure infusion of SSO_2 Therapy for a duration of 60 minutes and followed for 12 months. The FDA also specified that the primary effectiveness endpoint of infarct size would be evaluated with a superiority test, and that the powered primary safety composite endpoint, which includes death, stent thrombosis, major bleeding, reinfarction, new onset severe heart failure and possibly other adverse events, would be developed with an appropriate non-inferiority margin. We note that this study has not begun enrollment nor been completed.

In summary, while the applicant has submitted additional data to respond to our concerns, we do not believe that this data provides sufficient evidence that use of SSO_2 Therapy specifically results in improved mortality and heart failure outcomes among anterior STEMI patients. While there is room for outcomes improvement in mortality and heart failure rates post-PCI and stenting, we believe additional data is needed to demonstrate the effects of SSO_2 Therapy in improving these outcomes as compared to currently available therapies.

After consideration of all the information from the applicant, as well as the comments we received, we are unable to determine that SSO_2 Therapy represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for SSO_2 Therapy for FY 2021.

e. Eluvia™ Drug-Eluting Vascular Stent System (Eluvia)

Boston Scientific submitted an application for new technology add-on payments for the Eluvia™ Drug-Eluting Vascular Stent System for FY 2021. Eluvia™, a drug-eluting stent for the treatment of lesions in the femoropopliteal arteries, received FDA premarket approval (PMA) September 18, 2018. The applicant asserted that Eluvia™ was first commercially available on the market on October 4, 2018 and the first procedure with Eluvia™ following FDA approval in the U.S. occurred on October 5, 2018. We note that the applicant submitted an application for new technology add-on payments for FY 2020. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231), we stated that we remain concerned that we do not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing technologies. Therefore, we did not approve the Eluvia™ device for FY 2020 new technology add-on payments. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42220 through 42231) for a complete discussion regarding the Eluvia™ device's FY 2020 new technology application.

According to the applicant, the Eluvia™ system is a sustained release drug-eluting stent indicated for the treatment of lesions in the femoropopliteal arteries and is designed to restore blood flow in the peripheral arteries above the knee—specifically the superficial femoral artery (SFA) and proximal popliteal artery (PPA). The applicant asserted that this device/drug combination product for endovascular treatment of peripheral artery disease (PAD) utilizes a polymer that carries and protects the drug before and during the procedure and ensures that the drug is released into the tissue in a controlled, sustained manner to prevent the restenosis of the vessel. The applicant further asserted that Eluvia™ system's stent platform is purpose-built to address the mechanical challenges of the SFA with an optimal amount of strength, flexibility and fracture resistance. According to the applicant, Eluvia™'s polymer-based drug delivery system is uniquely designed to sustain the release of paclitaxel beyond 1 year to match the restenotic process in the SFA. The Eluvia™ system is indicated for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native SFA and/or PPA with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm, according to the applicant.

The applicant asserted that the Eluvia™ system is comprised of the implantable endoprosthesis and the stent delivery system. The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (nitinol). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The triaxial designed delivery system consists of an outer shaft to stabilize the stent delivery system, a middle shaft to protect and constrain the stent, and an inner shaft to provide a guidewire lumen. The delivery system is compatible with 0.035 in (0.89 mm) guidewires. The Eluvia™ stent is available in a variety of diameters and lengths. The delivery system is offered in two working lengths including 75 and 130 cm.

Peripheral artery disease (PAD) is a circulatory problem in which narrowed arteries reduce blood flow to the limbs, usually in the legs. Symptoms of PAD may include lower extremity pain due to varying degrees of ischemia and claudication, which is characterized by pain induced by exercise and relieved with rest. Risk factors for PAD include age ≥70 years; age 50 to 69 years with a history of smoking or diabetes; age 40 to 49 with diabetes and at least one other risk factor for atherosclerosis; leg symptoms suggestive of claudication with exertion, or ischemic pain at rest; abnormal lower extremity pulse examination; known atherosclerosis at other sites (for example, coronary, carotid, renal artery disease); smoking; hypertension, hyperlipidemia, and homocysteinemia.[98] PAD is primarily caused by atherosclerosis—the buildup of fatty plaque in the arteries. PAD can occur in any blood vessel, but it is more common in the legs than the arms. Approximately 8.5 million people in the United States have PAD, including 12–20% of individuals older than age 60.[99]

A diagnosis of PAD is established with the measurement of an ankle-brachial index (ABI) ≤0.9. The ABI is a comparison of the resting systolic blood pressure at the ankle to the higher systolic brachial pressure. Duplex ultrasonography is commonly used in conjunction with the ABI to identify the location and severity of arterial obstruction.[100]

Management of PAD is aimed at improving symptoms, improving functional capacity, and preventing amputations and death. Management of patients with lower extremity PAD may include medical therapies to reduce the risk for future cardiovascular events related to atherosclerosis, such as myocardial infarction, stroke, and peripheral arterial thrombosis. Such therapies may include antiplatelet therapy, smoking cessation, lipid-lowering therapy, and treatment of diabetes and hypertension. For patients with significant or disabling symptoms unresponsive to lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be needed. Surgical intervention includes angioplasty, a procedure in which a balloon-tip catheter is inserted into the artery and inflated to dilate the narrowed artery lumen. The balloon is then deflated and removed with the catheter. For patients with limb-threatening ischemia (for example pain while at rest and or ulceration), revascularization is a priority to reestablish arterial blood flow.

[98] Neschis, David G. & MD, Golden, M. (2018). Clinical features and diagnosis of lower extremity peripheral artery disease. Retrieved October 29, 2018, from *https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-lower-extremity-peripheral-artery-disease.*

[99] Centers for Disease Control and Prevention. (2018). Peripheral Arterial Disease (PAD) Fact Sheet. Retrieved from *https://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_PAD.htm.*

[100] Berger, J. & Davies, M. (2018). Overview of lower extremity peripheral artery disease. Retrieved October 29, 2018 from *https://www.uptodate.com/contents/overview-of-lower-extremity-peripheral-artery-disease.*

According to the applicant, treatment of the SFA is problematic due to multiple issues, including high rate of restenosis and significant forces of compression.

The applicant asserted that the Eluvia™ Drug-Eluting Vascular Stent System is a sustained-release drug-eluting self-expanding, nickel titanium alloy (nitinol) mesh stent used to reestablish blood flow to stenotic arteries. According to the applicant, the Eluvia™ system is the first stent specifically designed for deployment in the SFA and/or PPA that utilizes the anti-restenotic drug paclitaxel in conjunction with a polymer. Eluvia™ is built on the Innova™ Stent System platform, consisting of a self-expanding nitinol stent and an advanced, 6F low-profile triaxial delivery system for added support and placement accuracy. The Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis. The Eluvia™ Stent System is comprised of the implantable endoprosthesis and the stent delivery system (SDS).

According to the applicant, there are four principal treatment options for PAD, including two endovascular approaches (angioplasty and stenting):

- Medical therapy, typically for those with mild to medium symptoms. This may include pharmacotherapy (for example, cilostazil) and exercise therapy.
- Angioplasty, a procedure in which a catheter with a balloon on the tip is inserted into an artery and inflated to expand the artery and reduce the blockage. The balloon is then deflated and removed with the catheter. Some procedures use drug coated balloons, in which a drug is applied to the lesion at the time of balloon inflation.
- Stenting via a procedure in which a stent is placed in the artery to keep the artery open and prevent it from re-narrowing. This can be done with a bare metal stent or with a drug-eluting stent, which also releases a drug that helps slow the re-narrowing of the vessel.
- For patients with severe narrowing that is blocking blood flow, bypass surgery may be warranted. In the procedure, a healthy vein is used to make a new path around the narrowed or blocked artery.

The applicant further asserted that aside from Eluvia™, the alternative existing endovascular approaches (angioplasty and stenting) do not provide a sustained release application of a drug and that Eluvia™ is the first polymer-based, drug-eluting stent designed to treat and restore blood flow in the peripheral arteries above the knee, and the eluted medication helps to prevent tissue regrowth during the

entire period most commonly associated with restenosis. According to the applicant, the sustained release of the anti-restenotic drug is intentionally designed to elute over a 12–15-month period delivering the drug when restenosis is most likely to occur, which the applicant stated is a significantly longer period than the two-month duration of drug eluted from drug-coated balloons and the paclitaxel-coated Zilver PTX drug eluting stent.

The Eluvia™ stent system was granted approval for the following ICD–10–PCS procedure codes effective October 1, 2019:

ICD-10-PCS Code	Code Description
X27H385	Dilation of right femoral artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology group 5
X27H395	Dilation of right femoral artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27H3B5	Dilation of right femoral artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27H3C5	Dilation of right femoral artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27J385	Dilation of left femoral artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology Group 5
X27J395	Dilation of left femoral artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27J3B5	Dilation of left femoral artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27J3C5	Dilation of left femoral artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27K385	Dilation of proximal right popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology Group 5
X27K395	(Dilation of proximal right popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5)
X27K3B5	Dilation of proximal right popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27K3C5	Dilation of proximal right popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27L385	Dilation of proximal left popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology Group 5
X27L395	Dilation of proximal left popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New technology Group 5
X27L3B5	Dilation of proximal left popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27L3C5	Dilation of proximal left popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would therefore not be considered ''new'' for purposes of new technology add-on payments. We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42227), we stated that after consideration of the applicant's comments, we believe that the Eluvia™ device uses a unique mechanism of action to achieve a therapeutic outcome when compared to existing technologies such as the paclitaxel-coated stent. Therefore, we stated that the Eluvia™ device meets the newness criterion. We refer the reader to the FY 2020 final rule for the complete discussion of how the Eluvia™ device meets the newness criterion. The applicant noted in its FY 2021 application that for FY 2020, CMS concluded that the Eluvia™ device met the newness criterion. The applicant stated that it believes there is no basis for CMS to reach a contrary conclusion with regard to whether the Eluvia™ system meets the newness criterion for FY 2021. The applicant also reiterated that the Eluvia™ device uses a unique mechanism of action because it utilizes a sustained-release of a low-dose of

paclitaxel. In the proposed rule, we invited public comments on whether the Eluvia™ device is substantially similar to an existing technology and whether it meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021.

Comment: A commenter stated that total paclitaxel dose, not just dose density should be considered when comparing the Eluvia™ device to the Zilver® PTX for newness. The commenter noted the applicant's comparison of the dose density of paclitaxel for the polymer matrix vs the paclitaxel coated stent which as described by the applicant is 0.167ug/mm2 vs 3ug/mm2 respectively. The commenter stated that on the surface this statement may be technically accurate. However, according to the commenter, the Eluvia™ drug-eluting stent (DES) is coated on all surfaces with a permanent, non-degradable, polymer matrix containing paclitaxel. In comparison, the Zilver PTX DES is coated only on the abluminal (outer) surface of the stent that is in contact with the vessel wall after implantation. As a result, according to the commenter, when comparing the paclitaxel dose of the devices, the total dose should also be considered, not just the dose density. The commenter further stated that whereas the dose density suggests a ~18x decrease in the amount of paclitaxel used, the actual paclitaxel dose is only decreased <3x, and reporting only the dose density could lead the reader into underestimating the amount of paclitaxel contained on the Eluvia DES.

The commenter also noted that the applicant stated that ''Paclitaxel is released directly to the target lesion with the polymer matrix stent and that paclitaxel release is non-specific to the target lesion with paclitaxel-coated stents.'' According to the commenter, the clinical, scientific, or logical basis for this statement is unclear. The commenter further stated that the Eluvia™ DES is coated circumferentially with a paclitaxel-containing polymer matrix. The commenter stated that as a result of this historic coating technology that has been used on coronary stents initially approved by the FDA more than 15 years ago, the Eluvia stent releases paclitaxel circumferentially and nonspecific to the target lesion, which is only in contact with the abluminal surface of the stent. In contrast, as described above, the commenter stated that the Zilver PTX DES is only coated on the abluminal surface of the stent that is in contact with the treated vessel wall. Therefore, according to the commenter, the Zilver PTX releases paclitaxel directly to the target lesion in contrast with the nonspecific release of Eluvia.

The commenter further stated that avoiding the use of a polymer, if possible, is a preferred stent design. Additionally, the commenter noted that the applicant reiterates that the Eluvia™ device uses a unique mechanism of action because it utilizes a sustained release of a low-dose of paclitaxel. However, according to the commenter, this mechanism of action is neither new nor unique and has been used on coronary stents since approval of the first device in 2004. The commenter stated that newer technologies have advanced to use biodegradable polymer coatings or, like the Zilver PTX DES, eliminated the risk of a polymer coating altogether. According to the commenter, the ability to provide similar clinical outcomes without the need for a permanent, and potentially thrombogenic, polymer would seem to be the preferred technology. The commenter stated that research published in 2013 by authors from Boston Scientific, manufacturer of the Eluvia™ DES, have reported that the polymer of vinylidene fluoride–hexafluoropropylene (PVDF–HFP) polymer used on the Eluvia™ DES results in increased thrombogenicity compared with a bare metal stent: ''PVDF–HFP-coated struts exposed to blood flow offer a more thrombogenic surface compared with a bare luminal platinum-chromium (PtCr) stent, resulting in more initial thrombus and subsequently more neointima from thrombus organization.'' [101] The commenter concluded by supporting the benefits of short-term and polymer-free drug delivery like that offered by the Zilver PTX DES: ''our data suggest that short-term drug elution while polymer absorption occurs is biologically preferable to maintaining a continuous and permanent polymeric surface once drug elution has occurred. This approach offers the benefits of minimizing polymeric load, while avoiding chronic inflammatory reactions but maintaining the beneficial anti-proliferative effect.'' [102] The commenter stated that based on this published research by the manufacturer of the Eluvia™ DES, it is surprising that the Eluvia™ technology would be considered to meet newness standards as compared to the polymer-free Zilver PTX DES.

The applicant commented that the Eluvia™ system satisfies the newness criterion because it is recently FDA-approved and is not substantially similar to existing devices due to its new and unique polymer carrier-enabled mechanism of action. The applicant asserted that Eluvia™ is the first and only sustained-release drug-eluting stent for the treatment of lesions in the superficial femoral artery (SFA) and proximal popliteal artery (PPA). The applicant reiterated that Eluvia™ is significantly different from existing drug-coated stent technology, which lacks a mechanism for sustained and controlled release of paclitaxel. According to the applicant, the sustained-release mechanism the Eluvia™ system offers enables the use of significantly less paclitaxel compared to current stent technology to inhibit restenosis. The applicant also commented that in addition, Eluvia's stent platform is purpose-built to address the mechanical challenges of the SFA, balancing strength, flexibility and fracture resistance.

The applicant also noted CMS's concerns regarding newness expressed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42228) and provided the following reiteration of their FY2020 comments which compared the Eluvia™ to the Zilver® PTX (Zilver® drug-eluting peripheral stent). The applicant commented that the Eluvia™ device's mechanism of action is different from that of Zilver® PTX because the Eluvia™ device's polymer matrix layer allows for targeted, localized, sustained, low-dose amorphous paclitaxel delivery with minimal systemic distribution or particulate loss. The applicant provided a comparison of the polymer matrix stent vs the paclitaxel-coated stent. According to the applicant, the polymer matrix stent is encased in a polymer matrix, the paclitaxel-coated stent is not. The dose density of paclitaxel for the polymer matrix vs the paclitaxel coated stent is 0.167ug/mm2 vs 3ug/mm2. Paclitaxel is delivered to the lesion via a diffusion gradient with the polymer matrix stent whereas the paclitaxel-coated stent has no diffusion gradient. Paclitaxel is released directly to the target lesion with the polymer matrix stent. Paclitaxel release is non-specific to the target lesion with paclitaxel-coated stent. Paclitaxel is released over approximately 12–15

[101] Eppihimer MJ, et al. Impact of Stent Surface on Thrombogenicity and Vascular Healing—A Comparative Analysis of Metallic and Polymeric Surfaces. *Circ Cardiovasc Interv*. 2013;6(4):370–377, p. 376.

[102] Eppihimer MJ, et al. Impact of Stent Surface on Thrombogenicity and Vascular Healing—A Comparative Analysis of Metallic and Polymeric Surfaces. *Circ Cardiovasc Interv*. 2013;6(4):370–377, p. 377.

months with the polymer matrix stent. Paclitaxel release is complete at two months with paclitaxel coated stents.

The applicant also commented that CMS determined that Eluvia satisfied the newness and cost criteria in the FY2020 Final Rule and committed to ''monitor new information and recommendations as they become available.''

Response: We appreciate the comments received regarding the comparison of the polymer matrix Eluvia™ vs the paclitaxel-coated Zilver PTX with regard to the mechanism of action and newness. After consideration of the information provided by both the applicant and the commenter as to whether the Eluvia™ should be considered new for purposes of new technology add on payments, we agree with the applicant that Eluvia™ uses a unique mechanism of action because the sustained release of paclitaxel combats restenosis for 12–15 months as compared to other drug-coated balloons or drug-coated stents that deliver drug to the artery for about two months. Accordingly, after consideration of the comments, we believe that the Eluvia™ device uses a unique mechanism of action to achieve a therapeutic outcome when compared to existing technologies such as the paclitaxel-coated stent and therefore meets the newness criterion. As previously stated, the Eluvia™ device received FDA approval under a PMA on September 18, 2018. The device was first available on the U.S. market on October 4, 2018. We consider the beginning of the newness period to commence when Eluvia was first available on the U.S. market on October 4, 2018.

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 76 percent of identified claims. To identify potential cases where Eluvia™ could be utilized, the applicant searched the FY 2018 MedPAR file for ICD–10–PCS codes from the Peripheral Drug Eluting Stent and Peripheral Bare Metal Stent categories. For the analysis using 100 percent of cases, the applicant identified a total of 11,051 cases spanning 150 MS–DRGs. The applicant then removed charges for the technology being replaced. The applicant stated that because it was unable to determine a more specific percentage reduction, it chose the most conservative approach for calculation purposes and removed 100% of charges associated with service category Medical/Surgical Supply Charge Amount, which included revenue center 027x. The applicant then standardized the charges and applied an inflation factor of 11.1%, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule, to update the charges from FY 2018 to FY 2020 (84 FR 42629). The applicant added charges for the new technology by multiplying the cost of the technology by the national CCR for implantable devices (0.299) from the FY 2020 IPPS final rule. Under the analysis based on 100% of identified claims, the applicant determined an average case-weighted threshold amount of $100,851 and a final average inflated standardized charge per case of $157,343.

Under the analysis based on 76 percent of identified claims, the applicant used the same methodology, which identified 8,335 cases across 8 MS–DRGs. The applicant determined the average case-weighted threshold amount of $98,196 and a final inflated average standardized charge per case of $147,343. Because the final inflated average standardized charge per case exceeded the case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion. In the proposed rule, we invited public comments on whether Eluvia™ meets the cost criterion.

Comment: The applicant commented that the cost analysis, as summarized in the proposed rule, demonstrates that Eluvia™ meets the new technology add-on payment cost criterion. The applicant further commented that it analyzed the cost criterion associated with Eluvia in various scenarios utilizing different assumptions and that in each of these analyses, the cost criterion was achieved. The applicant noted that CMS did not express any concerns regarding any of the analyses provided and as such, the applicant maintained that Eluvia™ meets the cost criterion.

Response: We appreciate the applicant's comments concerning the cost criterion. Based on the cost analysis as summarized previously and after consideration of the public comments we received, we agree that the Eluvia™ device meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that Eluvia™ represents a substantial clinical improvement over existing technologies because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmission rates; reduces the rate of device related complications; and achieves similar functional outcomes and EQ–5D index values while associated with half the rate of TLRs.

As stated above, Boston Scientific submitted an application for new technology add-on payments for the Eluvia™ device for FY 2020 that was not approved. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231), we noted the FDA's preliminary review of data that identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices, and stated that we remained concerned that we did not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing technologies. The applicant resubmitted its application for new technology add-on payments for FY 2021 with updated two-year primary patency results to demonstrate that the Eluvia™ device represents a substantial clinical improvement over existing technologies. Below we summarize the studies the applicant submitted with both its FY 2020 and FY 2021 applications, followed by the new information the applicant submitted with its FY 2021 application to support that the technology represents a substantial clinical improvement.

The applicant submitted the results of the MAJESTIC study, a single-arm first-in-human study of Eluvia™. The MAJESTIC [103] study is a prospective, multicenter single-arm, open label study. Per the applicant, the MAJESTIC study demonstrated long-term treatment durability among patients whose femoropopliteal arteries were treated with the Eluvia™ stent. The MAJESTIC study enrolled 57 patients with symptomatic lower limb ischemia and lesions in the superficial femoral artery or proximal popliteal artery. Efficacy measures at 2 years included primary patency, defined as duplex ultrasound peak systolic velocity ratio of <2.5 and the absence of target lesion revascularization (TLR) or bypass. Safety monitoring through 3 years included adverse events and TLR. The 24-month clinic visit was completed by 53 patients; 52 had Doppler ultrasound evaluable by the core laboratory, and 48 patients had radiographs taken for stent fracture analysis. The 3-year follow-up was completed by 54 patients. At 2 years, 90.6% (48/53) of patients had improved by one or more Rutherford categories as compared with the pre-

[103] Müller-Hülsbeck S et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up. Cardiovasc Intervent Radiol. 2017 Dec; 40(12):1832–1838.

procedure level without the need for TLR (when those with TLR were included, 96.2% sustained improvement); only one patient exhibited a worsening in level, 66.0% (35/53) of patients exhibited no symptoms (category 0) and 24.5% (13/53) had mild claudication (category 1) at the 24-month visit. Mean ABI improved from 0.73 ± 0.22 at baseline to 1.02 ± 0.20 at 12 months and 0.93 ± 0.26 at 24 months. At 24 months, 79.2% (38/48) of patients had an ABI increase of at least 0.1 compared with baseline or had reached an ABI of at least 0.9. According to the applicant, the primary patency rate at 12 months was 96.4%. With regard to the Eluvia™ stent achieving superior primary patency, the applicant submitted the results of the IMPERIAL [104] trial in which the Eluvia™ stent is compared, head-to-head, to the Zilver® PTX® drug-eluting stent. The IMPERIAL study is a global, multi-center, randomized controlled trial consisting of 465 subjects. Eligible patients were aged 18 years or older and had symptomatic lower-limb ischemia, defined as Rutherford category 2, 3, or 4 and stenotic, restenotic (treated with a drug-coated balloon >12 months before the study or standard percutaneous transluminal angioplasty only), or occlusive lesions in the native superficial femoral artery or proximal popliteal artery, with at least one infrapopliteal vessel patent to the ankle or foot. Patients had to have stenosis of 70% or more (via angiographic assessment), vessel diameter between 4 mm and 6 mm, and total lesion length between 30 mm and 140 mm.

Subjects who had previously stented target lesion/vessels treated with drug-coated balloon <12 months prior to randomization/enrollment and subjects who had undergone prior surgery of the SFA/PPA in the target limb to treat atherosclerotic disease were excluded from the study. Two concurrent single-group (Eluvia™ only) sub studies were done: a non-blinded, non-randomized pharmacokinetic sub study and a non-blinded, non-randomized study of patients with long lesions (≤140 mm). The IMPERIAL study is a prospective, multicenter, single-blinded randomized, controlled (RCT) non-inferiority trial. Patients were randomized (2:1) to implantation of either a paclitaxel-eluting polymer stent (Eluvia™) or a paclitaxel-coated stent (Zilver® PTX®) after the treating physician had successfully crossed the target lesion with a guide wire. The primary endpoints of the study are Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or TLR through 12 months, and primary vessel patency at 12 months post-procedure. Secondary endpoints included the Rutherford categorization, Walking Impairment Questionnaire, and EQ–5D assessments at 1 month and 6 months post-procedure. Patient demographic and characteristics were balanced between Eluvia™ stent and Zilver® PTX® stent groups.

The applicant noted that lesion characteristics for the Eluvia™ stent vs Zilver® PTX® stent arms were comparable. Clinical follow-up visits related to the study were scheduled for 1 month, 6 months, and 12 months after the procedure, with follow-up planned to continue through 5 years, including clinical visits at 24 months and 5 years and clinical or telephone follow-up at 3 and 4 years.

The applicant asserted that in the IMPERIAL study, the Eluvia™ stent demonstrated superior primary patency over the Zilver® PTX® stent, with 86.8% vs. 77.5% respectively (p=0.0144). The non-inferiority primary efficacy endpoint was also met. The applicant asserted that the SFA presents unique challenges with respect to maintaining long-term patency. There are distinct pathological differences between the SFA and coronary arteries. The SFA tends to have higher levels of calcification and chronic total occlusions when compared to coronary arteries. Following an intervention within the SFA, the SFA produces a healing response which often results in restenosis or re-narrowing of the arterial lumen. This cascade of events leading to restenosis starts with inflammation, followed by smooth muscle cell proliferation and matrix formation.[105] Because of the unique mechanical forces in the SFA, this restenotic process of the SFA can continue well beyond 300 days from the initial intervention. Primary patency at 12 months, by Kaplan-Meier estimate, was significantly greater for Eluvia™ than for Zilver® PTX®, with 88.5% and 79.5% respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4% primary patency rate at 12 months in the MAJESTIC study, the single-arm first-in-human study of Eluvia™.

The IMPERIAL study included two concurrent single-group (Eluvia™ only) sub studies: a non-blinded, non-randomized pharmacokinetic sub study and a non-blinded, non-randomized study of patients with long lesions (>140 mm). For the pharmacokinetic sub study, patients had venous blood drawn before stent implantation, at intervals ranging from 10 minutes to 24 hours post implantation, and then at either 48 hours or 72 hours post implantation. The pharmacokinetics sub study confirmed that plasma paclitaxel concentrations after Eluvia™ implantation were well below thresholds associated with toxic effects in studies in patients with cancer (0·05 μM or ~43 ng/mL).

The IMPERIAL sub study long lesion subgroup consisted of 50 patients with average lesion length of 162.8 mm that were each treated with two Eluvia™ stents. Twelve-month outcomes for the long lesion subgroup are 87% primary patency and 6.5% TLR. In a subgroup analysis of patients 65 years and older (Medicare population), the primary patency rate in the Eluvia™ stent group is 92.6%, compared to 75.0% for the Zilver® PTX® stent group (p=0.0386).

With regard to reducing the rate of subsequent therapeutic interventions, secondary outcomes in the IMPERIAL study included repeat re-intervention on the same lesion, TLR. The rate of subsequent interventions, or TLRs, in the Eluvia™ stent group was 4.5% compared to 9.0% in the Zilver® PTX® stent group. The applicant asserted that TLR rate in the Eluvia™ group represents a substantial reduction in re-intervention on the target lesion compared to that of the Zilver® PTX® stent group.

With regard to decreasing the number of future hospitalizations or physician visits, the applicant asserted that the substantial reduction in the lesion revascularization rate led to a reduced need to provide additional intensive care, distinguishing the Eluvia™ group from the Zilver® PTX® group. In the IMPERIAL study, Eluvia™-treated patients required fewer days of re-hospitalization. There were 13.9 post procedure in-hospital days in the Eluvia™ group for all adverse events compared to 17.7 post procedure in-hospital days in the Zilver® PTX® group. There were 2.8 post procedure in-hospital days in the Eluvia™ group for TLR/Total Vessel Revascularization (TVR) compared to 7.1 post procedure in-hospital days in the Zilver® PTX® group. And lastly, there were 2.7 post-procedure in-hospital days from the

[104] Gray WA et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomised, non-inferiority trial. Lancet. 2018 Sep 24.

[105] Forrester JS, Fishbein M, Helfant R, Fagin J. A paradigm for restenosis based on cell biology: Clues for the development of new preventive therapies. J Am Coll Cardiol. 1991 Mar 1;17(3):758–69.

Eluvia™ group for procedure/device related adverse events compared to 4.5 post procedure in-hospital days for the Zilver® PTX® group.

With regard to reducing hospital readmission rates, the applicant asserted that patients treated in the Eluvia™ group experienced reduced rates of hospital readmission following the index procedure compared to those in the Zilver® PTX® group. Hospital readmission rates at 12 months were 3.9% for the Eluvia™ group compared to 7.1% for the Zilver® PTX® group. Similar results were noted at 1 and 6 months; 1.0% vs 2.6% and 2.4% vs 3.8% respectively.

With regard to reducing the rate of device related complications, the applicant asserted that while the rates of adverse events were similar in total between treatment arms in the IMPERIAL study, there were measurable differences in device-related complications. Device-related adverse-events were reported in 8% of patients in the Eluvia™ group compared to 14% of patients in the Zilver® PTX® group.

Lastly, with regard to achieving similar functional outcomes and EQ–5D index values, while associated with half the rate of TLRs, the applicant asserted that narrowed or blocked arteries within the SFA can limit the supply of oxygen-rich blood throughout the lower extremities, causing pain or discomfort when walking. The applicant further asserted that performing physical activities is often challenging because of decreased blood supply to the legs, typically causing symptoms to become more challenging overtime unless treated. The applicant asserted that while functional outcomes appear similar between the Eluvia™ and Zilver® PTX® groups at 12 months, these improvements for the Zilver® PTX® group are associated with twice as many TLRs to achieve similar EQ–5D index values.[106] At 12 months, of the patients with complete Rutherford assessment data, 241 (86 percent) of 281 patients in the Eluvia™ group and 120 (85 percent) of 142 patients in the Zilver® PTX® group had symptoms reported as Rutherford Category 0 or 1 (none to mild claudication). The mean ankle-brachial index was 1·0 (SD 0·2) in both groups at 12 months (baseline mean ankle-brachial index 0·7 [SD 0·2] for Eluvia™; 0·8 [0·2] for Zilver® PTX®), with sustained hemodynamic improvement for approximately 80 percent of the patients in both groups. Walking function improved significantly from baseline to 12 months in both groups, as measured with the Walking Impairment Questionnaire and the 6-minute walk test. In both groups, the majority of patients had sustained improvement in the mobility dimension of the EQ–5D and roughly half had sustained improvement in the pain or discomfort dimension. No significant between-group differences were observed in the Walking Impairment Questionnaire, 6-minute walk test, or EQ–5D. Secondary endpoint results for the Eluvia™ stent and Zilver® PTX® stent groups are as follows:

- Hemodynamic improvement in walking—80.8 percent versus 78.7 percent;
- Walking impairment questionnaire scores (change from baseline)—40.8 (36.5) versus 35.8 (39.5);
- Distance (change from baseline)—33.2 (38.3) versus 29.5 (38.2);
- Speed (change from baseline)—18.3 (29.5) versus 18.1 (28.7);
- Stair climbing (change from baseline)—19.4 (36.7) versus 21.1 (34.6); and
- 6-Minute walk test distance (m) (change from baseline)—44.5 (119.5) versus 51.8 (130.5).

As summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42230), in our discussion of the comments received regarding substantial clinical improvement with respect to the new technology add-on payment application for Eluvia™ for FY 2020, we received a comment expressing safety concerns with paclitaxel-coated devices used to treat PAD. The commenter stated they were aware of an FDA alert concerning paclitaxel-coated devices. The commenter stated the applicant and other manufacturers of devices using paclitaxel should consider an alternative to paclitaxel.

We stated in response that we were aware of FDA's March 15, 2019 letter to healthcare providers regarding the ''Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality''. We noted that in March 2019, FDA conducted a preliminary analysis of long-term follow-up data (up to 5 years in some studies) of the pivotal premarket randomized trials for paclitaxel-coated products indicated for PAD. We stated that while the analyses are ongoing, according to FDA, the preliminary review of the data had identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices.[107] Of the three trials with 5-year follow-up data, each showed higher mortality in subjects treated with paclitaxel-coated products than subjects treated with uncoated devices. In total, among the 975 subjects in these 3 trials, there was an approximately 50 percent increased risk of mortality in subjects treated with paclitaxel-coated devices versus those treated with control devices (20.1 percent versus 13.4 percent crude risk of death at 5 years).

We also noted that FDA stated that the data should be interpreted with caution for several reasons. First, there is large variability in the risk estimate of mortality due to the limited amount of long-term data. Second, the studies were not originally designed to be pooled, introducing greater uncertainty in the results. Third, the specific cause and mechanism of the increased mortality is unknown.

We further stated that based on the preliminary review of available data, FDA made the following recommendations regarding the use of paclitaxel-coated balloons and paclitaxel-eluting stents: That health care providers consider the following until further information is available; continue diligent monitoring of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents; when making treatment recommendations and as part of the informed consent process, consider that there may be an increased rate of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents; discuss the risks and benefits of all available PAD treatment options with your patients; for most patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents should generally be used until additional analysis of the safety signal has been performed; for some individual patients at particularly high risk for restenosis, clinicians may determine that the benefits of using a paclitaxel-coated product may outweigh the risks; ensure patients receive optimal medical therapy for PAD and other cardiovascular risk factors as well as guidance on healthy lifestyles including weight control, smoking cessation, and exercise.

We also noted that FDA further stated that paclitaxel-coated balloons and stents are known to improve blood flow

[106] Gray WA, Keirse K, Soga Y, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomized, non-inferiority trial. Lancet 2018; published online Sept 22. *http://dx.doi.org/10.1016/S0140–6736(18)32262–1.*

[107] *https://www.fda.gov/medical-devices/letters-health-care-providers/update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting.*

to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels. However, because of this concerning safety signal, FDA stated that it believes alternative treatment options should generally be used for most patients while FDA continues to further evaluate the increased long-term mortality signal and its impact on the overall benefit-risk profile of these devices. FDA stated it intends to conduct additional analyses to determine whether the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use. FDA stated it will also evaluate whether these analyses impact the safety of patients treated with these devices for other indications, such as treatment of arteriovenous access stenosis or critical limb ischemia.

Furthermore, we stated that because of concerns regarding this issue, FDA convened an Advisory Committee meeting of the Circulatory System Devices Panel on June 19 and 20, 2019 to: Facilitate a public, transparent, and unbiased discussion on the presence and magnitude of a long-term mortality signal; discuss plausible reasons, including any potential biological mechanisms, for a long-term mortality signal; re-examine the benefit-risk profile of this group of devices; consider modifications to ongoing and future U.S. clinical trials evaluating devices containing paclitaxel, including added surveillance, updated informed consent, and enhanced adjudication for drug-related adverse events and deaths; and guide other regulatory actions, as needed. The June 19 and 20, 2019 Advisory Committee meeting of the Circulatory System Devices Panel concluded that analyses of available data from FDA-approved devices show an increase in late mortality (between 2 and 5 years) associated with paclitaxel-coated devices intended to treat femoropopliteal disease.[108] However, causality for the late mortality rate increase could not be determined. Additional data may be needed to further assess the magnitude of the late mortality signal, determine any potential causes, identify patient subgroups that may be at greater risk, and to update benefit-risk considerations of this device class.[109]

We stated that FDA continues to recommend that health care providers report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents. FDA stated that it will keep the public informed as any new information or recommendations become available.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231), after consideration of the public comments we received and the latest available information from the FDA advisory panel, we noted the FDA panel's preliminary review of the data had identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices. We stated that additionally, since FDA has stated that it believes alternative treatment options should generally be used for most patients while it continues to further evaluate the increased long-term mortality signal and its impact on the overall benefit-risk profile of these devices, we remained concerned that we did not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing technologies. Therefore, we stated that we were not approving the Eluvia™ device for FY 2020 new technology add-on payments. We also stated that we would monitor any new information or recommendations as they become available.

Since the FY 2020 IPPS/LTCH PPS final rule, the FDA issued an August 7, 2019 update: ''Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality''.[110] In its update, the FDA included recommendations to healthcare providers for assessing and treating patients with PAD using paclitaxel-coated devices. Based on the FDA's review of available data and the Advisory Panel conclusions, the FDA recommends that healthcare providers consider the following:

- Continue diligent monitoring of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents.
- When making treatment recommendations, and as part of the informed consent process, consider that there may be an increased rate of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents.
- Discuss the risks and benefits of all available PAD treatment options with your patients. For many patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents provide a more favorable benefit-risk profile based on currently available information.
- For individual patients judged to be at particularly high risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality.
- In discussing treatment options, physicians should explore their patients' expectations, concerns and treatment preferences.
- Ensure patients receive optimal medical therapy for PAD and other cardiovascular risk factors as well as guidance on healthy lifestyles including weight control, smoking cessation, and exercise.
- Report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents.

In addition, the August 7, 2019 update noted the following. Based on the conclusions of its analysis and recommendations of the advisory panel, FDA stated that it is taking additional steps to address this signal, including working with manufacturers on updates to device labeling and clinical trial informed consent documents to incorporate information about the late mortality signal. FDA also stated that it is continuing to actively work with the manufacturers and investigators on additional clinical evidence development for assessment of the long-term safety of paclitaxel-coated devices. FDA noted that paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The update stated that the panel concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality).

The applicant stated in its FY 2021 application that while CMS denied the application for new technology add-on payments for Eluvia™ for FY 2020 because of its concerns about paclitaxel, the available evidence and policymaking from the FDA would suggest that this device is safe, effective and a substantial clinical improvement. To address the substantial clinical

[108] *https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-19-20-2019-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting#event-materials.*

[109] *https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-19-20-2019-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting#event-materials.*

[110] *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel.*

improvement concerns stated in the FY 2020 final rule, the applicant stated that Eluvia™ is not associated with increased all-cause mortality and that two-year all-cause mortality data are consistent with FDA-published rates for uncoated angioplasty devices. The applicant further asserted that most recent publications on peripheral paclitaxel-coated devices do not replicate the strong mortality signal identified in the meta-analysis. The applicant stated that it submitted information on Eluvia™ to the FDA for the June 19–20 Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. The applicant further asserted that the FDA continues to find that paclitaxel devices are effective, specifically that ''Paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices''.[111] The applicant stated that the FDA, following months of investigation, multiple letters to health care providers and an advisory panel meeting, has not changed the marketed status of peripheral paclitaxel devices. Therefore, the applicant respectfully requested that CMS consider that Eluvia™ satisfies the substantial clinical improvement criterion in light of this information. The applicant referred to the FDA's meta-analysis of long-term follow-up data from the pivotal premarket randomized trials for paclitaxel-coated devices used to treat PAD. The FDA's meta-analysis of these trials [112] identified a late mortality signal in study subjects treated with paclitaxel-coated devices compared to patients treated with uncoated devices. Specifically, in three randomized trials which enrolled a total of 1,090 patients, the crude mortality rate at 5 years was 19.8% (range 15.9%–23.4%) in patients treated with paclitaxel-coated devices compared to 12.7% (range 11.2%–14.0%) in subjects treated with uncoated devices. The relative risk for increased mortality at 5 years was 1.57 (95% confidence interval 1.16–2.13), which corresponds to a 57% relative increase in mortality in patients treated with paclitaxel-coated devices.

In its application for FY 2021, the applicant stated that they respectfully disagree with CMS's conclusion that Eluvia™ did not satisfy the substantial clinical improvement criterion as the IMPERIAL randomized controlled trial demonstrates superiority over the closest comparative device. In its application for FY 2021, in response to these concerns related to peripheral paclitaxel devices, the applicant referred to the updated bulletin FDA issued in August 2019 to provide the latest information on its analysis of long-term follow-up data from premarket trials and to provide summary information from its June 2019 advisory panel meeting. Specifically, the applicant noted that FDA stated that paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The June 2019 advisory panel concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality).

The applicant also noted that it has worked closely with FDA to address questions about the late mortality signal associated with some peripheral paclitaxel-coated devices, as identified in the meta-analysis. The applicant noted that Eluvia™ was not included in the meta-analysis.

Additionally, the applicant stated that it has demonstrated (a) the absence of a mortality signal with Eluvia™ and (b) the absence of a mortality signal with sustained-release drug eluting paclitaxel stent technology in the large long-term data for the TAXUS coronary stent.[113]

With regard to the absence of a mortality signal with Eluvia™, the applicant further stated that Eluvia™ is not associated with increased all-cause mortality. The applicant explained that Eluvia™ shows no mortality signal at 2 years in over 300 patients. Additionally, the applicant noted that its parent company Boston Scientific has extensive experience with sustained-release paclitaxel-eluting stent technology and noted that TAXUS has over 10 years of clinical data, with long-term mortality in clinical trials following approximately 2,800 patients, without an observed mortality signal.

As it relates to Eluvia™, the applicant stated that findings of the FDA analysis should be interpreted with caution for several reasons. First, Eluvia™ was not included in the FDA meta-analysis. Second, the applicant stated the analysis failed to find any plausible mechanism that could explain the observed mortality signal. Third, the applicant asserted that the analysis contained structural flaws that may have contributed to its findings, including small sample size, presence of ascertainment bias and lack of patient level data.

The applicant added that additional analyses have been conducted since the publication of the meta-analysis. In a Medicare claims analysis of over 150,000 patients who underwent femoropopliteal artery revascularization, the applicant noted that no mortality signal was seen in the group treated with paclitaxel-coated devices.[114] According to the applicant, this finding was echoed by other studies.

Finally, the applicant stated that it believes the FDA recognized the value of allowing physicians to treat their PAD patients with paclitaxel devices in its letter published on August 7, 2019, acknowledging the signal in the meta-analysis and recognizing the benefits that paclitaxel devices offer for these patients.

In summary, the applicant stated that Eluvia™ should be approved for new technology add-on payments based on the following:

- Updated August 2019 FDA letter to providers issued after the FY 2020 IPPS/LTCH PPS final rule, maintaining peripheral paclitaxel devices on the market;
- Multiple recently published studies[115] [116] demonstrating the absence of increased mortality associated with peripheral paclitaxel devices;
- An analysis of over 150,000 Medicare beneficiaries, designed with FDA input, demonstrating no difference in mortality between patients treated with peripheral paclitaxel devices

[111] FDA Letter to Health Care Providers, August 7, 2019. Last accessed at *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel* on September 10, 2019.

[112] *https://www.fda.gov/medical-devices/letters-health-care-providers/update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting.*

[113] Stone GW, Ellis SG, Colombo A, et al. Long-term safety and efficacy of paclitaxel-eluting stents final 5-year analysis from the TAXUS Clinical Trial Program. JACC Cardiovasc Interv. 2011;4(5):530–542.

[114] Secemsky EA at al. Drug-Eluting Stent Implantation and Long-Term Survival Following Peripheral Artery Revascularization. J Am Coll Cardiol. 2019 May 28;73(20):2636–2638.

[115] 18Spreen MI, Martens JM, Knippenberg B, et al. Long-Term Follow-up of the PADI Trial: Percutaneous Transluminal Angioplasty Versus Drug-Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia. *J Am Heart Assoc.* 2017;6(4).

[116] UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality—Letter to Health Care Providers. 2019; Last accessed at *https://www.fda.gov/MedicalDevices/Safety/LettertoHealthCareProviders/ucm633614.htm* on October 9, 2019.

compared to those treated without paclitaxel devices;

- Confounding factors in the 2018 JAHA Katsanos et al. meta-analysis (meta-analysis)[117] and ascertainment bias, as highlighted at the 2019 Vascular Leaders Forum,[118] and no plausible mechanism has been identified for increased mortality;
- The rate of mortality for patients treated with Eluvia™ at 2 years is consistent with the rate of non-paclitaxel-based peripheral devices.[119]

Although the Eluvia™ system was not included in the meta-analysis, in the proposed rule we stated that we were concerned with the conclusion of the meta-analysis results. Specifically, we stated that we were concerned with the conclusion that there is an increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limb and how it impacts substantial clinical improvement for the Eluvia™ system.

We also noted the FDA's statement in the August 2019 letter that because of the demonstrated short-term benefits of the devices, the limitations of the available data, and uncertainty regarding the long-term benefit-risk profile of paclitaxel-coated devices, the FDA believes clinical studies of these devices may continue and should collect long-term safety (including mortality) and effectiveness data. Per the FDA, these studies require appropriate informed consent and close safety monitoring to protect enrolled patients.

Comment: A commenter stated that the design of the MAJESTIC clinical study is inadequate to support a claim of substantial clinical improvement due to its small size, strict inclusion/exclusion criteria, and lack of a comparator group. According to the commenter, the MAJESTIC study is inadequate to demonstrate substantial clinical improvement and that use of this single arm study to support substantial clinical improvement should be considered with care due to the small (n=57) and highly selected patient population (for example, lesion length limited to a maximum of 11 cm). The commenter stated that although the applicant reports a very high primary patency rate of 96.4% at 12 months, this rate drops substantially to 77.9% at just 25 months, suggesting the potential of a late catch-up phenomenon as previously observed with other polymer-coated peripheral DES.[120] [121] The commenter also noted that the TLR rate appears to double each year (that is quadruple from year 1 to year 3), increasing from 3.6% at 1 year to 7.2% at 2 years to 14.7% at 3 years.[122]

The commenter also stated that there are errors in the published 1-year IMPERIAL study primary patency results, which is the primary endpoint of the study which require a correction of the 1-year publication and results. The commenter stated that although the errors have been identified, to their knowledge no correction to the paper has yet been published. As such, according to the commenter, the ability to understand the outcomes of this study, particularly patency, which is the primary endpoint of the study, is hindered.

The commenter also stated that patency results are inconsistently presented. The primary endpoint of 12-month patency was reported after the required sample size of 409 patients completed 12-month follow-up or had an endpoint event; these results indicate primary patency of 86.8% (231/266) for Eluvia vs. 81.5% (106/130) for Zilver PTX. However, a post-hoc analysis reports a larger difference of 86.8% (243/280) for Eluvia vs. 77.5% (110/142) for Zilver PTX. This represents an additional 14 Eluvia patients and 12 Zilver PTX patients compared to the primary analysis. While the results for the Eluvia patients are consistent between the primary and post-hoc analyses (86.8% [231/266] vs. 85.7% [12/14]), the results for the final 12 Zilver PTX patients added to the post-hoc analysis appear to be outliers who had significantly worse outcomes than the primary patient cohort (patency 77.5% [110/142] in primary cohort vs. 33.3% [4/12] in post-hoc cohort, p=0.002); according to the commenter, this raises questions about the pooling of data between the primary cohort and the post-hoc cohort that is used in the post-hoc analysis and reporting.

The commenter further stated that claims of ''superior primary patency'' and ''highest reported'' two-year primary patency are misleading. From the most recently presented two-year results (with data correction), there is no significant difference in patency between Eluvia and Zilver PTX at two years (83.0% vs. 77.1%, p=0.10, not significant). Based on these results, a claim of superior primary patency cannot be maintained, according to the commenter. The commenter also expressed concerns regarding the claim of ''highest reported'' two-year patency. The commenter stated that by its very nature, this claim can only be made by comparing results across numerous distinct clinical trials, each enrolling patients and analyzing outcomes based on study-specific criteria and variable definitions. For example, the commenter noted that the Zilver PTX randomized trial included the enrollment of patients with critical limb ischemia, a group with known poor outcomes that were excluded from the IMPERIAL trial. The Zilver PTX trial also had a more stringent definition for patency, requiring the peak systolic velocity ratio (PSVR) to be <2.0 for a lesion to be considered patent.[123] In comparison, in the IMPERIAL trial, the requirement for patency was a more lenient criterion of PSVR ≤2.4. The commenter stated that more concerning is that the definition of patency at two years in the IMPERIAL trial has been redefined to eliminate any patency failures that may have occurred prior to 730 days and is now defined as ''clinically-driven TLR up to 730 days and duplex ultrasound data at 24 months.'' This change in the definition can be observed by comparing the one-year Kaplan-Meier curves to the two-year curves and noting that patency at 24 months is actually increased compared with what was previously reported at 13 months; that is, patency failures occurring on imaging, but not resulting in a re-intervention have been eliminated prior to 730 days.[124] The

[117] *https://www.ahajournals.org/doi/full/10.1161/JAHA.118.011245.*

[118] Varcoe R. Unintended Consequences of Various trial Designs, Potential Effect on Mortality and Other Outcomes. Vascular Leaders Forum, March 2019.

[119] Pooled all-cause mortality rate includes IMPERIAL and MAJESTIC Trials. 2-year all-cause mortality rate for IMPERIAL (includes IMPERIAL RCT, Long Lesion, and PK sub-studies) is 7.0%. MAJESTIC follow-up is final at 3 years. IMPERIAL follow-up is complete through 2 years and ongoing through 5 years. As-treated ELUVIA patients. FDA PTA reference based on FDA Executive Summary. Two-year mortality rate within the PTA arm of ILLUMENATE was 7.4% and within the PTA arm of IN.PACT SFA was 1.0%.

[120] Duda SH, et al. Drug-eluting and Bare Nitinol Stents for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery: Long-Term Results From the SIROCCO Trial. J Endovasc Ther. 2006;13(6):701–710.

[121] Lammer J, et al. First Clinical Trial of Nitinol Self-Expanding Everolimus-Eluting Stent Implantation for Peripheral Arterial Occlusive Disease. J Vasc Surg. 2011;54(2):394–401.

[122] Müller-Hülsbeck S, et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up. Cardiovasc Intervent Radiol. 2017;40(12):1832–1838.

[123] Dake MD, et al. Durable Clinical Effectiveness With Paclitaxel-Eluting Stents in the Femoropopliteal Artery 5-Year Results of the Zilver PTX Randomized Trial. Circulation. 2016;133(15):1472–1483.

[124] Gray WA. 2-year Outcomes from the IMPERIAL Randomized Head to Head Study of Eluvia DES and Zilver PTX. Oral presentation at: The Leipzig Interventional Course (LINC) Annual Meeting; January 2020; Leipzig, Germany.

commenter stated that this modified definition is inconsistent with other studies, further highlighting the inability to appropriately compare data across studies.

The commenter also stated that the secondary randomization (that is, the provisional DES arm) of the Zilver PTX RCT was specifically excluded from this comparison. These Zilver PTX patients actually had a higher two-year primary patency rate of 83.4% compared with 83.0% for Eluvia. According to the commenter, this blanket claim of superiority appears to be in stark contrast to traditionally accepted criteria established by FDA to allow such superiority claims. The commenter further stated that the FDA has not indicated that Eluvia provides a substantial clinical improvement.

We also received a comment stating that section § 412.87(b) describes the eligibility criteria associated with the substantial clinical improvement criterion, specifically that it ''improves clinical outcomes relative to services or technologies previously available...'' The commenter stated that CMS' conclusions that there is insufficient evidence to determine substantial clinical improvement included in both the FY 2020 and 2021 rules does not articulate why the clinical trial information provided by the applicant is not sufficient. Instead, CMS relies on the potential signal described in the meta-analysis and the FDA review of the data on paclitaxel-coated devices.

The commenter further stated that despite the various deliberations by the FDA, it has not limited the use of paclitaxel devices and more importantly, CMS has not limited coverage of paclitaxel devices. Per the language in § 412.87(b), the substantial clinical improvement criterion is to be evaluated ''relative to services or technologies previously available.'' The commenter stated that it appears the applicant has provided a comparison of the Eluvia device to existing, comparable devices for the treatment of peripheral arterial disease. The commenter contended this is the data that should be utilized to determine if the technology represents a SCI.

The commenter also asserted that if the FDA had removed existing paclitaxel devices from the market, or CMS had issued non-coverage for paclitaxel devices at the national or local level based on the FDA analyses, they would concur that there would be insufficient data to determine SCI. The commenter stated that since the FDA has not materially changed the label for paclitaxel devices nor has CMS issued non-coverage policies for any paclitaxel devices, existing paclitaxel devices represent an appropriate comparison when evaluating substantial clinical improvement in the new technology add-on payment application as they represent a medically reasonable medical option for Medicare patients.

The commenter contended that the Eluvia™ device meets the substantial clinical improvement criterion as it showed superiority over the only other paclitaxel peripheral stent in a head-to-head randomized controlled trial, and that the results have been sustained based on longest follow up clinical data published to date for the Eluvia™ device.

The applicant commented that the IMPERIAL trial was designed as a non-inferiority study, as are many head-to-head trials of medical devices. Boston Scientific defined a pre-specified, post-hoc superiority analysis before evaluation of the clinical trial results; therefore, the non-inferiority and subsequent superiority testing methodology and results were not subjected to bias. The superiority testing was performed after the 12-month follow-up window for all enrolled subjects had closed.

According to the applicant, from a statistical perspective, the pre-specified success criteria for superiority used the same logic as the pre-specified success criteria for non-inferiority: ''ELUVIA will be concluded to be superior to Zilver PTX for device effectiveness if the one-sided lower 95% confidence bound on the difference between treatment groups in 12-month primary patency is greater than zero.'' The commenter stated that a more stringent one-sided lower 97.5% confidence bound (shown as two-sided 95% confidence interval) on the difference between treatment groups was observed to be greater than zero and the corresponding p-value was 0.0144.

In addition to the internal analysis performed by Boston Scientific, these data were published in The Lancet following its peer-review process. As stated in The Lancet, ''The superiority analysis of primary patency in the full-analysis cohort was a pre-specified post-hoc analysis'' and ''In this head-to-head randomized trial, the primary non-inferiority endpoints for efficacy and safety at 12 months were met, and post-hoc analysis of the 12-month patency rate showed superiority for Eluvia over Zilver PTX.'' [125] According to the applicant, these claims are non-misleading and supported by valid scientific evidence.

The applicant also provided a comment in response to CMS' request for comments on the implications of the recent meta-analysis addressing paclitaxel-coated balloons and stents. The applicant maintained that Eluvia™ is different from the devices evaluated in the meta-analysis. The applicant stated that as CMS noted, Eluvia™ was not addressed in the meta-analysis. Further, the applicant maintained that Eluvia™ delivers paclitaxel in much lower doses than the products discussed in the meta-analysis and is the only peripheral device to deliver paclitaxel through a sustained-release mechanism of action where delivery of paclitaxel is controlled and focused on the target lesion. Thus, according to the applicant, the suggestion in the meta-analysis of a late-term mortality risk associated with paclitaxel coated devices is not directly applicable to the Eluvia™ device. Boston Scientific submitted information (available at *https://www.fda.gov/media/127704/download*) to the FDA on paclitaxel relative to Eluvia™ in advance of FDA's June 19–20 Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting.

Consequently, the applicant does not believe that the findings of limited generalizability suggested in the meta-analysis should inhibit CMS from determining that Eluvia™ satisfies the substantial clinical improvement criterion.

The applicant further commented that given the differences between Eluvia™ and other peripheral paclitaxel coated devices, it would be more appropriate to examine safety considerations for Eluvia™ relative to products with similar mechanisms of action and dose levels, such as the Taxus coronary stent indicated in the treatment of lesions in native coronary arteries. Boston Scientific asserted that it has more experience with sustained-release drug-eluting stents than any other manufacturer. According to the applicant, Boston Scientific developed coronary sustained-release drug-eluting stent technology, first with its Taxus coronary drug-eluting stent. According to the applicant, the Eluvia™ and Taxus stents are similar in design intent and mechanism of action. We note that the Taxus stent involves the treatment of a different patient population. According to the applicant, with the same drug and comparable low-dose controlled drug elution profiles achieved via a polymer matrix, the Eluvia™ peripheral stent bears greater similarity to the Taxus

[125] Gray WA, Keirse K, Soga Y, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): a randomised, non-inferiority trial. *The Lancet.* 2018;392(10157):1541–1551.

coronary stent than to any peripheral paclitaxel-coated balloon or non-polymeric paclitaxel-coated stent with respect to design features and drug release kinetics. The applicant asserted that given the similarity in disease presentation for coronary and peripheral atherosclerotic lesions and the same anti-proliferative impact of paclitaxel on the lesions regardless of vessel bed, signals for any potential long-term systemic effects of targeted paclitaxel eluted from a stent polymer matrix would be apparent in patients treated with Taxus. Therefore, the applicant asserted that data on the controlled, localized and low dose paclitaxel elution by Taxus in the coronary or infrapopliteal vasculature can be used to gauge potential systemic effects of paclitaxel eluted from Eluvia™. According to the applicant, Taxus stent use has been extensively studied with more than 14 years of commercial experience and clinical trial data out to 10 years in patients with coronary[126] [127] [128] [129] implants and 5 years for those with infrapopliteal implants.

The applicant commented that in the Taxus stent family series of coronary studies, paclitaxel-based treatment showed consistent benefits compared to bare metal stenting and did not differentially affect long-term all-cause mortality as compared to bare stent treatment. Stone *et al.* report 5-year patient-level pooled results from nearly 2800 patients in randomized studies showing that all-cause mortality for patients treated with Taxus was similar to that of patients treated with the bare metal platform (9.8% vs 9.1%, p=0.53). The event rate analysis of mortality through 5 years for patients treated with Taxus (n=1400) compared to patients treated with the bare metal platform (n=1397) log-rank p=0.5283.

These analyses represent approximately triple the sample size of the studies with >2 year data included in the Katsanos meta-analysis and in FDA's analysis of 5-year data from paclitaxel-coated devices. In addition, long-term data from more than 4000 patients who received coronary Taxus in randomized and nonrandomized studies show mortality rates consistent with those expected for this patient population.[130] [131]

The applicant also commented that it remains questionable and unproven that the root cause of the observed higher mortality in certain retrospective meta-analyses has a direct relationship to the presence of paclitaxel in the evaluated devices. In the March 15 Letter to Health Care Providers,[132] the FDA observed, ''These data should be interpreted with caution for several reasons. First, there is large variability in the risk estimate of mortality due to the limited amount of long-term data. Second, these studies were not originally designed to be pooled, introducing greater uncertainty in the results. Third, the specific cause and mechanism of the increased mortality is unknown.''

The applicant commented that notably, the number of studies, patients, and devices contributing to the mortality calculations significantly decreased with the longer follow-up time frames. In addition, the applicant asserted that understanding possible effects of paclitaxel exposure is not possible without complete analysis of uniformly re-adjudicated patient level data, particularly with treatment arm crossover and previous interventions or subsequent re-interventions with paclitaxel-coated devices, which occurred in the analyzed studies.

The applicant commented that explanations unrelated to drug exposure may account for the signal observed in the meta-analysis by Katsanos et al.[133] These include preferential follow-up for control-arm patients (that is, more physician visits, closer monitoring, enhanced comorbidity management), which may improve survival in these arms. Not adjusting for between-arm imbalance of predisposing conditions or comorbidities associated with increased mortality risk in the cohort-level analysis could also contribute to a false signal.

The applicant further commented that currently, no plausible mechanistic link between paclitaxel and death has been postulated or established. To the contrary, the applicant stated that systemic paclitaxel infusions are known to improve survival among cancer patients.[134] [135] The periodically-repeated systemic doses of paclitaxel for chemotherapy are multiple orders of magnitude greater than the doses following treatment with either paclitaxel-coated devices[136] [137] [138] [139] or Eluvia™. The applicant stated that it is extremely unlikely that localized micro-doses associated with peripheral device use would have a negative effect on long-term survival.

The applicant commented that as no local vascular-based causes of mortality have been identified, any paclitaxel effect on mortality would occur via a systemic or non-vascular mechanism and would be apparent following paclitaxel exposure regardless of the administration route or implant location. The applicant asserted that no such effect on mortality was seen among thousands of patients who received a TAXUS paclitaxel-eluting coronary stent with a design very similar to that of Eluvia™, and no systemic effect should be expected with peripheral application.

[126] Yamaji K, Raber L, Zanchin T, et al. Ten-year clinical outcomes of first-generation drug-eluting stents: the Sirolimus-Eluting vs. Paclitaxel-Eluting Stents for Coronary Revascularization (SIRTAX) VERY LATE trial. Eur Heart J. 2016;37(45):3386–3395.

[127] Ormiston JA, Charles O, Mann T, et al. Final 5-year results of the TAXUS ATLAS, TAXUS ATLAS Small Vessel, and TAXUS ATLAS Long Lesion clinical trials of the TAXUS Liberte paclitaxel-eluting stent in de-novo coronary artery lesions. Coron Artery Dis. 2013;24(1):61–68.

[128] Kereiakes DJ, Cannon LA, Dauber I, et al. Long-term follow-up of the platinum chromium TAXUS Element (ION) stent: The PERSEUS Workhorse and Small Vessel trial five-year results. Catheter Cardiovasc Interv. 2015;86(6):994–1001.

[129] Stone GW, Ellis SG, Colombo A, et al. Long-term safety and efficacy of paclitaxel-eluting stents final 5-year analysis from the TAXUS Clinical Trial Program. JACC Cardiovasc Interv. 2011;4(5):530–542.

[130] Shishehbor MH, Goel SS, Kapadia SR, et al. Long-term impact of drug-eluting stents versus baremetal stents on all-cause mortality. J Am Coll Cardiol. 2008;52(13):1041–1048.

[131] Bravata DM, Gienger AL, McDonald KM, et al. Systematic review: the comparative effectiveness of percutaneous coronary interventions and coronary artery bypass graft surgery. Ann Intern Med. 2007;147(10):703–716.

[132] UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality—Letter to Health Care Providers. 2019; *https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCare Providers/ucm633614.htm*. Accessed April 15, 2019, 2019.

[133] Katsanos K, Spiliopoulos S, Kitrou P, Krokidis M, Karnabatidis D. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. J Am Heart Assoc. 2018;7(24): e011245.

[134] Ferguson T, Wilcken N, Vagg R, Ghersi D, Nowak AK. Taxanes for adjuvant treatment of early breast cancer. Cochrane Database Syst Rev. 2007(4):CD004421.

[135] Ghersi D, Willson ML, Chan MM, Simes J, Donoghue E, Wilcken N. Taxane-containing regimens for metastatic breast cancer. Cochrane Database Syst Rev. 2015(6):CD003366.

[136] BD announces new 300-mm length for Lutonix 018 DCB. Endovascular Today. March 2, 2020.

[137] Speck U, Cremers B, Kelsch B, et al. Do pharmacokinetics explain persistent restenosis inhibition by a single dose of paclitaxel? Circ Cardiovasc Interv. 2012;5(3):392–400.

[138] Yazdani SK, Pacheco E, Nakano M, et al. Vascular, downstream, and pharmacokinetic responses to treatment with a low dose drug-coated balloon in a swine femoral artery model. Catheter Cardiovasc

Interv. 2014;83(1):132–140.

[139] Scheinert D, Duda S, Zeller T, et al. The LEVANT I (Lutonix paclitaxel-coated balloon for the prevention of femoropopliteal restenosis) trial for femoropopliteal revascularization: first-in-human randomized trial of low-dose drug-coated balloon versus uncoated balloon angioplasty. JACC Cardiovasc Interv. 2014;7(1):10–19.

Response: We appreciate the comments received from the applicant and other commenters.

CMS has always considered all evidence in its decision whether a technology represents a substantial clinical improvement over existing technologies. We refer the commenter to the regulations at § 412.87 which states a new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Some highlights of what we consider includes the following but not limited to are:

- The totality of the circumstances when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- The totality of the information otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished information sources from within the United States or elsewhere such as clinical trials, peer reviewed journal articles, study results, meta-analyses, consensus statements and white papers may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Information sources we consider are listed including ''other appropriate information sources may be considered''.

We believe the IMPERIAL and MAJESTIC trials show a number of improved outcomes such as primary patency rates and decreased need for subsequent interventions. As stated above, the applicant provided the following two-year results from the IMPERIAL global randomized controlled clinical trial, comparing Eluvia™ to Zilver® PTX®:

- Eluvia™ maintains higher primary patency than Zilver® PTX® at 2 years, 83.0% compared to 77.1%. The applicant contended that guidelines recognize the importance of primary patency in assessing the efficacy of peripheral endovascular therapies.[140]
- Eluvia™'s tw2-year primary patency is the highest reported in a superficial femoral artery US pivotal trial for a drug-eluting stent or drug-coated balloon.[141] Per the applicant, the 2-year primary patency results are consistent with the 2-year TLR results released earlier in 2019.[142] According to the applicant, Eluvia™ sustained a statistically significant reduction in TLR at 2 years compared to Zilver PTX, 12.9% vs. 20.5% (p=0.0472).[143]
- In a subgroup analysis of patients 65 years and older (Medicare population), the primary patency rate in the Eluvia™ stent group is 92.6%, compared to 75.0% for the Zilver® PTX® stent group (p=0.0386).

Additionally, after the FY 2020 IPPS/LTCH final rule last year, as noted above, in its August 7, 2019 update, the FDA stated that ''Paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The Panel concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality).'' [144] Furthermore, per the FDA August 2019 update, ''for individual patients judged to be at particularly high risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality.'' [145] We expect that clinicians will discuss the risks and benefits of all available PAD treatment options with patients and that they will continue to diligently monitor patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents. We will continue to monitor the data and any further information provided by the FDA regarding the Eluvia™ system. Therefore, based on the above, we believe the Eluvia™ system represents a substantial clinical improvement over existing technologies.

After consideration of the public comments we received and for the reasons discussed, including the IMPERIAL and MAJESTIC trials which show a number of improved outcomes and the FDA August 7, 2019 update which concluded that the benefits of paclitaxel-coated devices (for example, reduced reinterventions) should be considered in individual patients along with potential risks (for example, late mortality) as well as for individual patients judged to be at particularly high risk for restenosis and repeat femoropopliteal interventions, clinicians may determine that the benefits of using a paclitaxel-coated device outweigh the risk of late mortality, we believe Eluvia™ represents a substantial clinical improvement over existing technologies. Therefore, we have determined that the Eluvia™ system meets all of the criteria for approval of new technology add-on payments for FY 2021. Cases involving Eluvia™ that are eligible for new technology add-on payments will be identified by the following ICD–10–PCS procedure codes:

[140] Writing Committee Members, Gerhard-Herman MD, Gornik HL et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: Executive Summary. Vasc Med. 2017 Jun; 22(3):NP1–NP43.

[141] Highest two-year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.

[142] BSC Data on File. As-treated ELUVIA and PTxControl data from IMPERIAL RCT.FDA PTA reference based on FDA Executive Summary (median of PTA arms).Abbreviations: DES, drug-eluting stent; TLR, target lesion revascularization; PTx, paclitaxel.

[143] Boston Scientific Presentation to the Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting, June 19, 2019.

[144] *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel.*

[145] *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel.*

ICD-10-PCS Code	Code Description
X27H385	Dilation of right femoral artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology group 5
X27H395	Dilation of right femoral artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27H3B5	Dilation of right femoral artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27H3C5	Dilation of right femoral artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27J385	Dilation of left femoral artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology Group 5
X27J395	Dilation of left femoral artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27J3B5	Dilation of left femoral artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27J3C5	Dilation of left femoral artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27K385	Dilation of proximal right popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology Group 5
X27K395	(Dilation of proximal right popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5)
X27K3B5	Dilation of proximal right popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27K3C5	Dilation of proximal right popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27L385	Dilation of proximal left popliteal artery with sustained release drug-eluting intraluminal device, percutaneous approach, New Technology Group 5
X27L395	Dilation of proximal left popliteal artery with two sustained release drug-eluting intraluminal devices, percutaneous approach, New technology Group 5
X27L3B5	Dilation of proximal left popliteal artery with three sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5
X27L3C5	Dilation of proximal left popliteal artery with four or more sustained release drug-eluting intraluminal devices, percutaneous approach, New Technology Group 5

According to the applicant, the cost per case for the Eluvia™ device is $5,610. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the costs of the new medical service or technology, or 65 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, the maximum new technology add-on payment for a case involving the use of the Eluvia™ device is $3,646.50 for FY 2021.

f. GammaTile

GT Medical Technologies, Inc. submitted an application for new technology add-on payments for FY 2021 for the GammaTile™. We note that Isoray Medical, Inc. and GammaTile, LLC previously submitted an application for new technology add-on payments for GammaTile™ for FY 2018, which was withdrawn, and also for FY 2019; however, the technology did not receive FDA marketing authorization by July 1, 2018 and, therefore, was not eligible for consideration for new technology add-on payments for FY 2019. GT Medical Technologies, Inc. submitted an application for FY 2020, which was not approved as CMS was unable to make a determination that GammaTile™ technology represents a substantial clinical improvement over existing therapies.

The GammaTile™ is a brachytherapy device for use in the treatment of patients who have been diagnosed with recurrent intracranial neoplasms, which uses cesium-131 radioactive sources embedded in a collagen matrix. GammaTile™ is designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of recurrent brain tumors. According to the applicant, the GammaTile™ constitutes a new form of internal radiation, with collagen tile structural offsets acting as an internal compensator for the delivery of cesium-131 brachytherapy sources embedded within the product. The applicant stated that the technology has been manufactured for use in the setting of a craniotomy resection site where there is a high chance of local

recurrence of a Central Nervous System (CNS) or dual-based tumor. The applicant asserted that the use of the GammaTile™ technology provides a new, unique modality for treating patients who require radiation therapy to augment surgical resection of malignancies of the brain. By offsetting the radiation sources with a 3mm gap of a collagen matrix, the applicant asserted that the use of the GammaTile™ technology resolves issues with ''hot'' and ''cold'' spots associated with brachytherapy, improves safety, and potentially offers a treatment option for patients with limited or no other available options. The GammaTile™ is biocompatible and bioabsorbable, and is left in the body permanently without need for future surgical removal. The applicant asserted that the commercial manufacturing of the product will significantly improve on the process of constructing customized implants with greater speed, efficiency, and accuracy than is currently available, and requires less surgical expertise in placement of the radioactive sources, allowing a greater number of surgeons to utilize brachytherapy techniques in a wider variety of hospital settings.

The GammaTile™ technology received FDA Section 510(k) clearance as a medical device on July 6, 2018. According to the applicant, due to finalization of design and manufacturing activities, the technology was not commercially available until January of 2019. Subsequently, the FDA cleared GammaTile™ as a Class II medical device under the corporate name of GT Medical Technologies, Inc. on March 13, 2019. The cleared indications for use state that GammaTile™ is intended to deliver radiation therapy (brachytherapy) in patients who have been diagnosed with recurrent intercranial neoplasms. The applicant submitted a request for approval for a unique ICD–10–PCS code for the use of the GammaTile™ technology, which was approved effective October 1, 2017 (FY 2018). The ICD–10–PCS procedure code used to identify procedures involving the use of the GammaTile™ technology is 00H004Z (Insertion of radioactive element, cesium-131 collagen implant into brain, open approach).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would therefore not be considered ''new'' for purposes of new technology add-on payments. We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42261), we stated that after consideration of comments, we believe that the GammaTile™ mechanism of action is different from current forms of radiation therapy and brachytherapy as it is the first FDA cleared device to use a manufactured collagen matrix which offsets radiation sources for use for the treatment of recurrent intracranial neoplasms. Therefore, we stated that the GammaTile™ is not substantially similar to existing brachytherapy technology and meets the newness criterion. We refer the reader to the FY 2020 final rule for the complete discussion of how the GammaTile™ meets the newness criterion. We invited public comments on whether the GammaTile™ is substantially similar to an existing technology and whether it meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021, but did not receive any additional comments. We continue to believe that the GammaTile™ is not substantially similar to existing brachytherapy technology and meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant worked with the Barrow Neurological Institute at St. Joseph's Hospital and Medical Center (St. Joseph's) to obtain actual claims from mid-2015 through mid-2016 for craniotomies that did not involve placement of the GammaTile™ technology. The cases were assigned to MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). For the 460 claims, the average case-weighted unstandardized charge per case was $143,831. The applicant standardized the charges for each case and inflated each case's charges by applying the outlier charge inflation factor of 1.054 included in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629) by the age of each case (that is, the factor was applied to 2015 claims 4 times and 2016 claims 3 times). The applicant then calculated an estimate for ancillary charges associated with placement of the GammaTile™ device, as well as standardized charges for the GammaTile™ device itself. The applicant determined it meets the cost criterion because the final inflated average caseweighted standardized charge per case (including the charges associated with the GammaTile™ device) of $270,445 exceeds the average case-weighted threshold amount of $151,193 for MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), the MS–DRG that would be assigned for cases involving the GammaTile™ device.

The applicant stated that its analysis does not include a reduction in costs due to reduced operating room times. According to the applicant, the cost analysis reflects the time associated with a craniotomy and device placement. The applicant does not anticipate any reduction in operating room time relative to prior operative methods. We invited public comments on whether the GammaTile™ technology meets the cost criterion. We did not receive any additional comments. Based on the analysis above, we believe that GammaTile™ meets the cost criterion.

With regard to substantial clinical improvement, the applicant stated that the GammaTile™ technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments for recurrent CNS malignancies and significantly improves clinical outcomes when compared to currently available treatment options. The applicant explained that therapeutic options for patients who have been diagnosed with large or recurrent brain metastases are limited (for example, stereotactic radiotherapy, additional EBRT, or systemic immunochemotherapy). However, according to the applicant, the GammaTile™ technology provides a treatment option for patients who have been diagnosed with radiosensitive recurrent brain tumors that are not eligible for treatment with any other currently available treatment options. Specifically, the applicant stated that the GammaTile™ device may provide the only radiation treatment option for patients who have been diagnosed with tumors located close to sensitive vital brain sites (for example, brain stem) and patients who have been diagnosed with recurrent brain tumors who may not be eligible for additional treatment involving the use of external beam radiation therapy. There is a lifetime limit for the amount of radiation therapy a specific area of the body can receive. Patients whose previous treatment includes external beam radiation therapy may be precluded from receiving high doses of radiation associated with subsequent external beam radiation therapy, and the GammaTile™ technology can also be used to treat tumors that are too large for treatment with external beam radiation therapy. According to the applicant,

patients who have been diagnosed with these large tumors are not eligible for treatment with external beam radiation therapy because the radiation dose to healthy brain tissue would be too high.

The applicant summarized how the GammaTile™ technology improves clinical outcomes compared to existing treatment options, including external beam radiation therapy and other forms of brain brachytherapy as: (1) Providing a treatment option for patients with no other available treatment options; (2) reducing the rate of mortality compared to alternative treatment options; (3) reducing the rate of radiation necrosis; (4) reducing the need for re-operation; (5) reducing the need for additional hospital visits and procedures; and (6) providing more rapid beneficial resolution of the disease process treatment.

The applicant cited several sources of data to support these assertions. The applicant referenced a paper by Brachman, Dardis et al., which was published in the *Journal of Neurosurgery* on December 21, 2018.[146] This study, a follow-up on the progress of 20 patients with recurrent previously irradiated meningiomas, is a feasibility or superior progression-free survival study comparing the patient's own historical control rate against subsequent treatment with GammaTile™.

An additional source of clinical data is from Gamma Tech's internal review of data from two centers treating brain tumors with GammaTile™; the two centers are the Barrow Neurological Institute (BNI) at St. Joseph's Hospital and St. Joseph's Medical Center, Phoenix, AZ, and this internal review is referred to here as the ''BNI'' study.[147] The BNI study summarized Gamma Tech's experience with the GammaTile™ technology. The applicant also included a reference to its updated study, described on ClinicalTrials.gov under NCT03088579, which includes 79 recurrent, previously irradiated intracranial neoplasms.

Another source of data that the applicant cited to support its assertions regarding substantial clinical improvement is an abstract by Pinnaduwage, D., et al. Also submitted in the application were abstracts from 2014 through 2018 in which updates from the progression-free survival study and the BNI study were presented at specialty society clinical conferences. The following summarizes the findings cited by the applicant to support its assertions regarding substantial clinical improvement.

Regarding the assertion of local control, the 2018 article which was published in the *Journal of Neurosurgery* found that, with a median followup of 15.4 months (range 0.03–47.5 months), there were 2 reported cases of recurrence out of 20 meningiomas, with median treatment site progression time after surgery and brachytherapy with the GammaTile™ precursor and prototype devices not yet being reached, compared to 18.3 months in prior instances. Median overall survival after resection and brachytherapy was 26 months, with 9 patient deaths. In a presentation at the Society for Neuro-Oncology in November 2014,[148] the outcomes of 20 patients who were diagnosed with 27 tumors covering a variety of histological types treated with the GammaTile™ prototype were presented. The applicant noted the following with regard to the patients: (1) All tumors were intracranial, supratentorial masses and included low and high-grade meningiomas, metastases from various primary cancers, high-grade gliomas, and others; (2) all treated masses were recurrent following treatment with surgery and/or radiation and the group averaged two prior craniotomies and two prior courses of external beam radiation treatment; and (3) following surgical excision, the prototype GammaTile™ were placed in the resection cavity to deliver a dose of 60 Gray to a depth of 5 mm of tissue; and (4) all patients had previously experienced regrowth of their tumors at the site of treatment and the local control rate of patients entering the study was 0 percent.

With regard to outcomes, the applicant stated that, after their initial treatment, patients had a median progression-free survival time of 5.8 months; post treatment with the prototype GammaTile™, at the time of this analysis, only 1 patient had progressed at the treatment site, for a local control rate of 96 percent; and median progression-free survival time, a measure of how long a patient lives without recurrence of the treated tumor, had not been reached (as this value can only be calculated when more than 50 percent of treated patients have failed the prescribed treatment).

The applicant stated that it received two peer-reviewed awards for comprehensive clinical trial reporting on the treatment of 79 recurrent brain tumors treated with GammaTile. The applicant provided a recent summary presentation titled: ''Surgically Targeted Radiation Therapy: A Prospective Trial in 79 Recurrent, Previously Irradiated Intracranial Neoplasms'' at *The American Brachytherapy Society*.[149] The clinical endpoints included time to tumor progression and survival, which the applicant stated provided objective, clinically important measures. The median local control after GammaTile therapy versus prior treatment was 12.0 versus 9.5 months for high-grade glioma patients (p=0.13) and 48.8 months versus 23.3 months for meningioma patients (p=0.01). For the metastasis patients, the median local control had not been reached versus 5.1 months with prior treatment (p=0.02). The median overall survival was 12.0 months for high grade glioma patients, 12.0 months for brain metastasis patients, and 49.2 months for the meningioma patients. According to the applicant, these data demonstrate dramatic, clinically meaningful difference in Kaplan-Meier curves comparing time to local recurrence at same site in the same patients. The applicant stated that GammaTile™ is significantly outperforming the initial therapies attempted in this patient population.

The applicant also cited the findings from Brachman, et al. to support local control of recurrent brain tumors. At the Society for Neuro-Oncology Conference on Meningioma in June 2016,[150] a second set of outcomes on the prototype GammaTile™ was presented. This study enrolled 16 patients with 20 recurrent Grade II or III meningiomas, who had undergone prior surgical excision and external beam radiation therapy. These patients underwent surgical excision of the tumor, followed by adjuvant radiation therapy with the prototype GammaTile™. The applicant noted the following outcomes: (1) Of the 20 treated tumors, 19 showed no evidence of radiographic progression at

[146] Brachman, D., et al., ''Resection and permanent intracranial brachytherpay using modular, biocompatible cesium-131 implants: Results in 20 recurrent previously irradiated meningiomas,'' *J Neurosurgery,* December 21, 2018.

[147] Brachman, D., et al., ''Surgery and Permanent Intraoperative Brachytherapy Improves Time to Progress of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology Conference on Meningioma, June 2016.

[148] Dardis, C., ''Surgery and Permanent Intraoperative Brachytherapy Improves Times to Progression of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology, November 2014.

[149] Brachman D, Youssef E, Dardis C, et al.: Surgically Targeted Radiation Therapy: Safety Profile of Collagen Tile Brachytherapy in 79 Recurrent, Previously Irradiated Intracranial Neoplasms on a Prospective Clinical Trial. Brachytherapy 18 (2019) S35–36.

[150] Brachman, D., et al., ''Surgery and Permanent Intraoperative Brachytherapy Improves Time to Progress of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology Conference on Meningioma, June 2016.

last follow-up, yielding a local control rate of 95 percent; 2 of the 20 patients exhibited radiation necrosis (1 symptomatic, 1 asymptomatic); and (2) the median time to failure from the prior treatment with external beam radiation therapy was 10.3 months and after treatment with the prototype GammaTile™ only 1 patient failed at 18.2 months. Therefore, according to the applicant, the median treatment site progression-free survival time after the prototype GammaTile™ treatment had not yet been reached (average follow-up of 16.7 months, range 1 to 37 months).

A third prospective study was accepted for presentation at the November 2016 Society for Neuro-Oncology annual meeting.[151] In this study, 13 patients who were diagnosed with recurrent high-grade gliomas (9 with glioblastoma and 4 with Grade III astrocytoma) were treated in an identical manner to the cases previously described. Previously, all patients had failed the international standard treatment for high-grade glioma, a combination of surgery, radiation therapy, and chemotherapy referred to as the ''Stupp regimen.'' For the prior therapy, the median time to failure was 9.2 months (range 1 to 40 months). After therapy with a prototype GammaTile™, the applicant noted the following: (1) The median time to same site local failure had not been reached and 1 failure was seen at 18 months (local control 92 percent); and (2) with a median follow-up time of 8.1 months (range 1 to 23 months) 1 symptomatic patient (8 percent) and 2 asymptomatic patients (15 percent) had radiation-related MRI changes. However, no patients required re-operation for radiation necrosis or wound breakdown. Dr. Youssef was accepted to present at the 2017 Society for Neuro-Oncology annual meeting, where he provided an update of 58 tumors treated with the GammaTile™ technology. At a median whole group follow-up of 10.8 months, 12 patients (20 percent) had a local recurrence at an average of 11.33 months after implant. 6- and 18-month recurrence-free survival was 90 percent and 65 percent, respectively. Five patients had complications, at a rate that was equal to or lower than rates previously published for patients without access to the GammaTile™ technology.

In support of its assertion of a reduction in radiation necrosis, the applicant also included discussion of a presentation by D.S. Pinnaduwage, Ph.D., at the August 2017 annual meeting of the American Association of Physicists in Medicine. Dr. Pinnaduwage compared the brain radiation dose of the GammaTile™ technology with other radioactive seed sources. Iodine-125 and palladium-103 were substituted in place of the cesium-131 seeds. The study reported findings that other radioactive sources reported higher rates of radiation necrosis and that ''hot spots'' increased with larger tumor size, further limiting the use of these isotopes. The study concluded that the larger high-dose volume with palladium-103 and iodine-125 potentially increases the risk for radiation necrosis, and the inhomogeneity becomes more pronounced with increasing target volume. The applicant also cited a presentation by Dr. Pinnaduwage at the August 2018 annual meeting of the American Association of Physicists in Medicine, in which research findings demonstrated that seed migration in collagen tile implantations was relatively small for all tested isotopes, with Cesium-13 showing the least amount of seed migration.

The applicant asserted that, when considered in total, the data reported in these presentations and studies and the intermittent data presented in their abstracts support the conclusion that a significant therapeutic effect results from the addition of GammaTile™ radiation therapy to the site of surgical removal. According to the applicant, the fact that these patients had failed prior best available treatments (aggressive surgical and adjuvant radiation management) presents the unusual scenario of a salvage therapy outperforming the current standard of care. The applicant noted that follow-up data continues to accrue on these patients.

Regarding the assertion that GammaTile™ reduces mortality, the applicant stated that the use of the GammaTile™ technology reduces rates of mortality compared to alternative treatment options. The applicant explained that studies on the GammaTile™ technology have shown improved local control of tumor recurrence. According to the applicant, the results of these studies showed local control rates of 92 percent to 96 percent for tumor sites that had local control rates of 0 percent from previous treatment. The applicant noted that these studies also have not reached median progression-free survival time with follow-up times ranging from 1 to 37 months. Previous treatment at these same sites resulted in median progression-free survival times of 5.8 to 10.3 months.

The applicant further stated that the use of the GammaTile™ technology reduces rates of radiation necrosis compared to alternative treatment options. The applicant explained that the rate of symptomatic radiation necrosis in the GammaTile™ clinical studies of 5 to 8 percent is substantially lower than the 26 percent to 57 percent rate of symptomatic radiation necrosis requiring re-operation historically associated with brain brachytherapy, and lower than the rates reported for initial treatment of similar tumors with modern external beam and stereotactic radiation techniques. The applicant indicated that this is consistent with the customized and ideal distribution of radiation therapy provided by the GammaTile™ technology.

The applicant also asserted that the use of the GammaTile™ technology reduces the need for re-operation compared to alternative treatment options. The applicant explained that patients receiving a craniotomy, followed by external beam radiation therapy or brachytherapy, could require re-operation in the following three scenarios:

- Tumor recurrence at the excision site could require additional surgical removal;
- Symptomatic radiation necrosis could require excision of the affected tissue; and
- Certain forms of brain brachytherapy require the removal of brachytherapy sources after a given period of time.

However, according to the applicant, because of the high local control rates, low rates of symptomatic radiation necrosis, and short half-life of cesium-131, the GammaTile™ technology will reduce the need for re-operation compared to external beam radiation therapy and other forms of brain brachytherapy.

Additionally, the applicant stated that the use of the GammaTile™ technology reduces the need for additional hospital visits and procedures compared to alternative treatment options. The applicant noted that the GammaTile™ technology is placed during surgery, and does not require any additional visits or procedures. The applicant contrasted this improvement with external beam radiation therapy, which is often delivered in multiple fractions that must be administered over multiple days. The applicant provided an example where whole brain radiotherapy (WBRT) is delivered over 2 to 3 weeks, while the placement of the GammaTile™ technology occurs during

[151] Youssef, E., ''C–131 Implants for Salvage Therapy of Recurrent High Grade Gliomas,'' Society for Neuro-Oncology Annual Meeting, November 2016.

the craniotomy and does not add any time to a patient's recovery.

Based on consideration of all of the previously presented data, the applicant believed that the use of the GammaTile™ technology represents a substantial clinical improvement over existing technologies. We noted in the proposed rule that the clinical data submitted as of that time in connection with its application for new technology add-on payments for FY 2021 is essentially identical to what was submitted in connection with its application for new technology add-on payments for FY 2020. As we indicated in previous rulemaking (84 FR 42260 through 42265), the findings presented appear to be derived from relatively small case-studies and not data from clinical trials conducted under an FDA-approved investigational device exemption application. We noted that the study performed on 74 patients with 79 tumors was a single-arm and single-institution study, where each patient functioned as their own control and the study goal was to compare the time to local recurrence after GammaTile™ treatment to the time of local recurrence after initial treatment of intracranial tumors. That is, the control arm were patients treated for initial intracranial brain tumors, and the treatment arm or the GammaTile™ treatment arm were the same control patients now experiencing local recurrent intracranial brain tumors in the same site with the same brain tumor type. In this clinical trial, the applicant compared the time from initial treatment to first local recurrence (control arm) vs. time from GammaTile™ treatment of first local recurrence to second local recurrence of the same brain tumor site and tumor type. There was a statistically significant difference between the control arm treatment and GammaTile™ treatment for patients with recurrent meningioma and brain metastases and no statistically significant difference between the control arm treatment and GammaTile™ treatment for patients with recurrent high-grade glioma.

We stated in the proposed rule that we continue to have concerns that, while the applicant described increases in median time to disease recurrence for certain intra-cranial tumors (in a small number of patients with different histologies) in support of clinical improvement, the lack of analysis, meta-analysis, or statistical tests indicates that the clinical efficacy and safety data for seeded brachytherapy is limited. While we acknowledged the difficulty in establishing randomized control groups in studies involving recurrent brain tumors, we stated that we are concerned that GammaTile™ technology does not represent a substantial clinical improvement over existing therapies and requires additional clinical data to demonstrate substantial clinical improvement. We noted that the applicant has stated its intention to provide additional clinical data and information in connection with its application for new technology add-on payments for FY 2021, potentially including an update on patient outcomes from the completed clinical trial (ClinicalTrials.gov, NCT03088579), additional clinical data from early adopting locations, and additional meta-analysis to address the concerns previously raised by CMS.

We invited public comments on whether the GammaTile™ technology meets the substantial clinical improvement criterion.

Comment: The applicant submitted a comment providing additional clinical data and information to support a determination of substantial clinical improvement, including updated clinical data from the pivotal clinical trial on GammaTile™, additional clinical data from early adopting clinical locations, and results from a systematic literature review, meta-analyses, and analyses of historic controls. The applicant submitted new data and analyses as evidence to support GammaTile™'s substantial clinical improvement for the treatment of three types of brain tumors: Recurrent high-grade gliomas; recurrent meningiomas; and recurrent metastatic brain tumors. According to the applicant, the single arm pivotal clinical trial on GammaTile™ limited enrollment to patients who were unable to receive other forms of radiation therapy.

The applicant included new data to show substantial clinical improvement using GammaTile™ for recurrent high-grade gliomas. They reported updated data from the pivotal trial demonstrating a median overall survival (OS) of 16.7 months and a median progression free survival (PFS) of 12.9 months for 40 patients with high-grade gliomas receiving GammaTile™ plus bevacizumab, with a mean follow-up time of 10.7 months. The applicant also reported results from a meta-analysis comparing median overall survival for recurrent high-grade gliomas with a range of comparators, and noted the median OS using GammaTile™ plus bevacizumab, external beam radiotherapy plus bevacizumab, bevacizumab, resection, Optune®, and best supportive care were 16.7 months, 10.1 months, 9.7 months, 7.3 months, 6.6 months, and 4.8 months, respectively. The applicant stated there was a statistically significant difference for GammaTile™ plus bevacizumab versus surgical resection alone ($p<0.001$), as well as for GammaTile™ plus bevacizumab versus best supportive care ($p<0.001$). The applicant noted there was insufficient publicly available information to perform statistical comparisons of GammaTile™ plus bevacizumab versus either external beam radiotherapy plus bevacizumab or bevacizumab alone.[152] The applicant also conducted a systematic literature review and selected a total of 16 articles with 695 patients for analysis. According to the applicant, the literature review and meta-analysis included a total of nine articles involving the treatment of recurrent high-grade gliomas in 522 patients. Of these nine studies, three utilized interstitial high-dose rate brachytherapy (HDR), one utilized interstitial low-dose rate brachytherapy (LDR), one utilized intracavitary HDR, and four utilized intracavitary LDR techniques. The applicant stated it could not perform statistical analyses on these outcomes due to the small number of studies and inconsistent reporting of OS and PFS. According to the applicant, the pooled meta-analysis for high-grade gliomas showed the mean rate of radiation necrosis requiring surgical intervention using traditional brachytherapy was 3.0 percent (standard error [SE]=1.0 percent),[153] whereas in the pivotal trial involving GammaTile™, 0 percent of patients treated with GammaTile™ for recurrent glioblastoma reported radiation necrosis requiring surgical intervention.[154]

The applicant cited two abstracts submitted to the 2020 annual Congress of Neurological Surgeons and 2020 annual meeting of the Society for Neuro-Oncology to report updated data on GammaTile™ treatment for recurrent meningiomas. According to the applicant, the updated data from the single arm pivotal clinical trial on GammaTile™ with a median follow-up of 25 months demonstrated a 6-month

[152] Brachman D, Nakaji P, Smith K, et al. Resection and Surgically Targeted Radiation Therapy for Treatment of Recurrent GBM. (submitted to the 2021 American Association of Neurological Surgeons (AANS) Annual Scientific Meeting).

[153] Choi M, Zabramski, JM. Re-irradiation Using Brachytherapy for Recurrent Intracranial Tumors: A Systematic Review and Meta-analysis of the Literature. (submitted to Cureus).

[154] Brachman D, Nakaji P, Smith K, et al. Resection and Surgically Targeted Radiation Therapy for Treatment of Recurrent GBM. (submitted to the 2021 American Association of Neurological Surgeons (AANS) Annual Scientific Meeting).

PFS rate of 100 percent for the 28 patients with 35 recurrent, previously-irradiated meningioma tumors treated with surgical resection plus GammaTile™ treatment. Additionally, the applicant asserted that the 3-year PFS rate matches the 2-year PFS rate (72 percent and 72 percent, respectively) for the patients included in the trial. The applicant noted that median time to progression had not been reached (95 percent CI > 35.6 months).[155] The applicant also noted that individuals with recurrent meningioma tumors treated with chemotherapeutic agents without radiation have a 6-month PFS rate of 26 percent,[156] and those who received stereotactic radiosurgery have 3-year PFS of 55%.[157] The applicant stated GammaTile™ treatment provides a substantial clinical improvement for recurrent meningioma tumors over existing treatment options considering the differences between reported 6-month, 2-year, and 3-year PFS rates.

The applicant noted that in the update of the GammaTile™ pivotal trial which included 29 recurrent meningiomas, there were statistically significant improvements in treatment site local control achieved with resection plus GammaTile™ versus the prior most recent treatments in the same patients. The applicant stated local control at 24 months was 51.7 percent with prior treatment versus 89.7 percent with GammaTile™ (hazard ratio [HR]=0.2 [p=0.0008]).[158] The applicant noted that the pivotal trial showed significant improvement in prognosis for patients with recurrent meningiomas. According to the applicant, the Cox's regression comparing the time-to-progression of the prior therapy to that of the GammaTile™ therapy produced a log-rank test with a p-value of 0.0008. The applicant stated that the median time to progression was 18.3 months in the prior period, but with a median study follow-up time of 15.4 months and only 2 failures, the median time to progression in the GammaTile™ period had not been reached, nor was it close.[159] According to the applicant, it performed a pooled meta-analysis of 16 articles with 695 patients, and included four articles involved in the treatment of recurrent meningioma tumors in 87 patients. The applicant stated that results from the meta-analysis showed a mean rate of radiation necrosis of 17.3 percent (SE=5.0 percent) and a mean rate of radiation necrosis requiring surgical intervention of 11.9 percent (SE=5.3 percent),[160] whereas in the pivotal trial involving treatment of recurrent meningioma using GammaTile™, 6% of patients had radiation necrosis and 0 percent of patients had radiation necrosis requiring surgical intervention.[161]

The applicant cited two abstracts submitted to the 2020 annual meeting of the Society for Neuro-Oncology Metastases and 2020 annual Congress of Neurological Surgeons as well as an unpublished manuscript submitted to *World Neurosurgery* to report updated data on GammaTile™ treatment for recurrent brain metastases. The applicant reported updated data from the single arm pivotal clinical trial on GammaTile™ for 12 previously-irradiated brain metastases treated with surgery and re-irradiation via permanently implanted GammaTile™ brachytherapy. The applicant reported that, with a median follow-up of 9.5 months, the median time to progression after the prior standard of care treatments was 4.8 months (95 percent CI; 1.9–22.0 months) and has not yet been reached after GammaTile™ therapy (95 percent CI gives a lower limit of at least 10.9 months). The applicant stated that when looking at all patients by tumor size, Kaplan-Meier estimated local control at 1 year for all tumors, tumors <2.5 cm, and >2.5 cm was 83 percent, 100 percent, and 75 percent, respectively. The applicant stated that with site-level frailty term, the HR=0.052 (p=0.0073; 95 percent CI = 0.006–0.452). Following a systematic review of the clinical literature, the applicant cited an MD Anderson Cancer Center postoperative resection cavity study, which evaluated 64 patients with completed resected brain metastases who were randomized to stereotactic radiosurgery (SRS) versus observation, at median follow-up of 11.1 months. According to the applicant, in the SRS arm, 1-year local control for all metastases, small metastases (<2.5cm), and large metastases (≤2.5cm) were 72 percent, 91 percent, and 40–46 percent, respectively.[162] The applicant asserted that compared to the MD Anderson Cancer Center study, which was a primary cited example in guidance from the RANO Brain Metastases Working Group, GammaTile™ treatment offers a clear and substantial clinical improvement.

According to the applicant, it performed a pooled meta-analysis of 16 articles with 695 patients, and included three articles involved in the treatment of recurrent brain metastases in 86 patients. The applicant stated it could not perform statistical analyses on these outcomes due to the small number of studies and inconsistent reporting of PFS and OS. The applicant stated that results from the meta-analysis showed mean rates of symptomatic radiation necrosis and radiation necrosis requiring surgical intervention of 22.4 percent (SE=7.0 percent) and 10.0 percent (SE=7.3 percent), respectively,[163] whereas in the pivotal trial involving GammaTile™, 8 percent and 0 percent of patients treated with

[155] Rogers L, Nakaji P, Youssef E, et al. Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma: Results from a Prospective Trial. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Rogers L, Nakaji P, Youssef E, et al. A Prospective Trial of Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma. (submitted to the 2020 Society for Neuro-Oncology (SNO) Annual Meeting).

[156] Kaley T, Barani I, Chamberlain M, et al. Historical Benchmarks for Medical Therapy Trials in Surgery- and Radiation-Refractory Meningioma: A RANO Review. *Neuro Oncol.* 2014;16:829–40.

[157] Kim M, Lee DH, Kim Rn HJ, et al. Analysis of the results of recurrent intracranial meningiomas treated with re-radiosurgery. *Clin Neurol Neurosurg.* 2017;153:93–101.

[158] Rogers L, Nakaji P, Youssef E, et al. Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma: Results from a Prospective Trial. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Rogers L, Nakaji P, Youssef E, et al. A Prospective Trial of Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma. (submitted to the 2020 Society for Neuro-Oncology (SNO) Annual Meeting).

[159] Rogers L, Nakaji P, Youssef E, et al. Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma: Results from a Prospective Trial. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Rogers L, Nakaji P, Youssef E, et al. A Prospective Trial of Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma. (submitted to the 2020 Society for Neuro-Oncology (SNO) Annual Meeting).

[160] Choi M, Zabramski, JM. Re-irradiation Using Brachytherapy for Recurrent Intracranial Tumors: A Systematic Review and Meta-analysis of the Literature. (submitted to Cureus).

[161] Rogers L, Nakaji P, Youssef E, et al. Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma: Results from a Prospective Trial. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Rogers L, Nakaji P, Youssef E, et al. A Prospective Trial of Resection and Surgically Targeted Radiation Therapy for Initial or Salvage Treatment of Aggressive Meningioma. (submitted to the 2020 Society for Neuro-Oncology (SNO) Annual Meeting).

[162] Mahajan A, Ahmed S, McAleer MF, et al. Post-Operative Stereotactic Radiosurgery versus Observation for Completely Resected Brain Metastases: A Single-Centre, Randomised, Controlled, Phase 3 Trial. *Lancet Oncol.* 2017;18:1040–1048; Alexander BM, Brown PD, Ahluwalia MS, et al. Clinical Trial Design for Local Therapies for Brain Metastases: A Guideline by the Response Assessment in Neuro-Oncology Brain Metastases Working Group. *Lancet Oncol.* 2018;19:e33-e42.

[163] Choi M, Zabramski, JM. Re-irradiation Using Brachytherapy for Recurrent Intracranial Tumors: A Systematic Review and Meta-analysis of the Literature. (submitted to Cureus).

GammaTile ™ for recurrent brain metastases reported symptomatic radiation necrosis and radiation necrosis requiring surgical intervention, respectively.[164]

The applicant noted that in the update of the GammaTile ™ pivotal trial which included 12 recurrent brain metastases, there were statistically significant improvements in treatment site local control achieved with resection plus GammaTile ™ versus the prior most recent treatments in the same patients. The applicant stated local control at 6 months was 41.7 percent with prior treatment versus 100 percent with resection plus GammaTile ™; at 12 months, local control was 33.3 percent with prior treatment versus 83.3 percent with resection plus GammaTile ™ (HR=0.052 [p = 0.0073]).[165] The applicant noted that the pivotal trial showed significant improvement in prognosis for patients with recurrent brain metastases. According to the applicant, the Cox's regression comparing the time-to-progression of the prior therapy to that of the GammaTile ™ therapy produced a log-rank test with a p-value of 0.0073. The applicant stated that the median time to progression was 4.8 months in the prior period, but with a median study follow-up time of 9.5 months and only 1 failure, the median time to progression in the GammaTile ™ period had not been reached, nor was it close.[166]

The applicant stated that it conducted a survey of 27 early adopters at 14 institutions who were involved in 51 commercial cases involving use of the GammaTile ™ device for treatment of recurrent brain tumors. The applicant asserted that the survey reported an overall adverse event/complication rate occurring during the 30 days following surgery of 3.8 percent, below the expected complication rate ranging from 9–40 percent that has been reported for intracranial neoplasm surgery.[167]

The applicant also claimed that GammaTile ™ therapy provides a substantial clinical improvement because use of GammaTile ™ therapy leads to a substantially decreased number of future visits to radiation oncology centers and to more rapid resolution of adjuvant radiation therapy treatment. According to the applicant, as the only truly available adjuvant radiation therapy for recurrent brain tumors that can be administered at the time of surgical excision, GammaTile ™ provides individuals access to adjuvant radiation therapy who otherwise are unable or unlikely to return for multiple follow-up visits for other forms of radiation therapy. According to the applicant, this substantial clinical improvement is critically important for many Medicare beneficiaries who live in distant rural areas and individuals in low-income households who are unlikely to return for follow-up due to socio-economic factors, and for individuals who are fearful or at high-risk if exposed to COVID–19 while traveling on public transportation, staying in hotels, or otherwise participating in follow-up radiation therapy visits.

The applicant further stated that CMS data demonstrates the unique ICD–10–PCS code for GammaTile™ that maps to MS–DRG 023 results in significantly more reimbursement for large, urban academic institutions as compared to smaller, community-based non-academic hospitals. The applicant asserted that approving new technology add-on payments for GammaTile™ will enable adoption in community and non-urban hospitals, improving both access to care and outcomes for patients by leveling the playing field for all institutions.

Other commenters expressed their support for GammaTile™ meeting the substantial clinical improvement criterion. Several commenters noted that GammaTile™ provides a safe and effective treatment option for a patient population that is in great need of new treatment options, especially given that individuals with recurrent brain cancer often are poor candidates for other forms of repeat same-site irradiation. Several commenters stated there was a growing body of evidence confirming that GammaTile™ therapy is well tolerated and improves local tumor control and survival.

Some commenters stated their direct experience with GammaTile™ therapy has been positive, and that they have seen lower complication rates than would otherwise be expected in these complex patients who are at higher risk for complications due to their prior treatments. A commenter referenced studies demonstrating the clinical outcomes involving the recurrent tumor (treated with GammaTile™) exceeded the outcomes achieved during the prior attempt to treat the tumor in the same patient. The commenter noted the superior outcomes with GammaTile™ occurred despite the fact that recurrent tumors are known to be more aggressive and faster moving, and also despite the fact that the patients were older at the time of recurrence.

Some commenters suggested that GammaTile™ therapy reduces the physical and financial burden of treatment for brain tumor patients by reducing the number of physician visits required for radiation therapy. Some commenters also noted that the ''one-and-done'' aspect of GammaTile™ therapy reduces caregiver burden and provides a radiation treatment option that minimizes the need for exposure to other individuals during travel and participation in follow-up visits, which is especially important during the ongoing COVID–19 public health emergency. Several commenters asserted that GammaTile™ therapy ensures 100 percent patient compliance since it is implanted at the time of surgery. A commenter noted their support for patient access to GammaTile™ because of the large proportion of their cancer center patients who travel well over an hour from their home to receive post-

[164] Brachman D, Nakaji P, Smith K, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (accepted to 2020 Society for Neuro-Oncology (SNO) Metastasis Annual Meeting; Nakaji P, Youssef E, Smith K, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Nakaji P, Smith K, Youssef E, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (submitted to World Neurosurgery).

[165] Brachman D, Nakaji P, Smith K, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (accepted to 2020 Society for Neuro-Oncology (SNO) Metastasis Annual Meeting; Nakaji P, Youssef E, Smith K, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Nakaji P, Smith K, Youssef E, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (submitted to World Neurosurgery).

[166] Brachman D, Nakaji P, Smith K, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (accepted to 2020 Society for Neuro-Oncology (SNO) Metastasis Annual Meeting; Nakaji P, Youssef E, Smith K, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (submitted to the 2020 Congress of Neurological Surgeons (CNS) Annual Meeting); Nakaji P, Smith K, Youssef E, et al. A Prospective Trial of Resection Plus Surgically Targeted Radiation Therapy for Brain Metastasis. (submitted to World Neurosurgery).

[167] Brachman DG, Youssef E, Dardis CJ, et al. Resection and Permanent Intracranial Brachytherapy Using Modular, Biocompatible Cesium-131 Implants: Results in 20 Recurrent, Previously Irradiated Meningiomas. *J Neurosurg.* 2018;131:1819–1828; Ferreira C, Parham A, Chen C, et al. First Experience with GammaTile Permanent Implants for Recurrent Brain Tumors. *Neuro-Oncology.* 2019;i:216; Wong JM, Panchmatia JR, Ziewacz JE, et al. Patterns in Neurosurgical Adverse Events: Intracranial Neoplasm Surgery. *Neurosurg Focus.* 2012;33:E16; Brachman D, Youssef E, Dardis C, et al. Surgically Targeted Radiation Therapy: Safety Profile of Collagen Tile Brachytherapy in 79 Recurrent, Previously Irradiated Intracranial Neoplasms on a Prospective Clinical Trial. *Brachytherapy, An International Multidisciplinary Journal.* 2019;18:S35–S36.

resection radiation treatments, and having to travel that far has a negative impact on patient compliance.

Response: We thank the commenters for their comments, including the updated data and additional analyses provided by the applicant to address the concerns discussed in the proposed rule.

After further review, including review of the additional clinical data and information submitted by the applicant, CMS continues to have concerns with respect to whether GammaTile™ meets the substantial clinical improvement criterion for approval for new technology add-on payments. While the updated pivotal trial data provided by the applicant in its comment compared the treatment of the recurrent tumor with GammaTile™ to the prior most recent treatments in the same patients for all three tumor types, we have concerns that a primary tumor and tumor recurrence may not be comparable diseases and therefore question whether the pivotal trial data is appropriate for the purposes of evaluating substantial clinical improvement. Furthermore, the applicant provided data from abstracts and an unpublished manuscript submitted for publication to report updated data on the GammaTile™ pivotal trial for recurrent meningiomas and recurrent brain metastases, but did not provide statistical data or meta-analyses that demonstrate significant efficacy of GammaTile™ when compared to conventional radiation therapy. The applicant also performed a meta-analysis for each of the 3 cancer sub-types, which showed the only improvement in overall survival for patients treated with GammaTile™ was for those with high-grade gliomas when treated in combination with bevacizumab when compared to surgery alone, but not other modalities. The meta-analyses looking at recurrent meningiomas and recurrent brain metastases did not show statistically significant improvements in clinical outcomes. Furthermore, the authors of the systematic literature review and meta-analyses noted the limitations of the study, including the small number of studies available on same site reirradiation using brachytherapy for recurrent brain tumors. Moreover, the vast majority of studies included in the literature review and meta-analyses included no randomization and no control group in their study designs. While the applicant provided summary results for the meta-analyses showing outcomes for GammaTile™ when compared to existing treatments (as well as the studies used), we have concerns that we are unable to determine superiority for GammaTile™ without any data analysis and methods for these meta-analyses.

After review of all data received to date, we continue to have the same concerns as noted in the FY 2020 final rule and the FY 2021 proposed rule, discussed previously. Therefore, based on the information stated above, we are unable to make a determination that GammaTile™ technology represents a substantial clinical improvement over existing therapies, and we are not approving new technology add-on payments for the GammaTile™ for FY 2021.

g. Hemospray® Endoscopic Hemostat

Cook Medical submitted an application for new technology add-on payments for the Hemospray ® Endoscopic Hemostat (Hemospray) for FY 2021. According to the applicant, Hemospray is indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding. Using an endoscope to access the gastrointestinal tract, the Hemospray delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site without making contact with the GI tract wall. The Hemospray powder, bentonite, is propelled through the application catheter, either a 7 or 10 French polyethylene catheter, by release of CO_2 from the cartridge located in the device handle and sprayed onto the bleeding site. According to the applicant, bentonite can rapidly absorb 5 to 10 times its weight in water and swell up to 15 times its dry volume, becoming cohesive to itself and adhesive to tissue forming a physical barrier to aqueous fluid (for example, blood). Hemospray powder is not absorbed by the body and does not require removal as it passes through the GI tract within 72 hours. Hemospray is single-use and disposable.

According to the applicant, current standard of care hemostatic modalities used for the management of nonvariceal gastrointestinal bleeding have a failure rate of 8 to 15 percent and a rebleeding rate of 10 to 25 percent, or worse, depending on patient etiology and morbidity.[168] The applicant asserted that the risk of morbidity, mortality, and rebleeding can be predicted using validated scoring methods such as the Rockall Score (RS).[169] Cancerous lesions, which are more frequently identified as a result of advances in locating and determining the cause of bleeding,[170] have lower rates of hemostasis (as low as 40 percent), with higher recurrent bleeding rates (over 50 percent within 1 month), with high 3 month mortality.[171] [172] Continued bleeding that is not controlled by conventional techniques, or recurrent bleeding from the same lesion, may be treated by repeated attempts at endoscopic hemostasis, interventional radiology hemostasis (IRH) with guided transarterial embolization (TAE), or surgery.[173] According to the applicant, a recent systematic review found minimally invasive rescue options like TAE had re-bleeding rates that were higher than those from surgery with no significant difference in mortality.[174] According to the applicant, patients who are not surgical candidates have very few options for ''rescue'' when conventional hemostasis techniques fail.

The applicant asserted that, in addition to increased morbidity and mortality, the financial impact of failure to achieve hemostasis is considerable. Based on a retrospective claims analysis by the applicant of the 2012 MedPAR file and the Provider of Services file, 13,501 cases were identified which showed all-cause mortality for patients requiring more than 1 endoscopy (6%), IRH (9%), or surgery (14%) was significantly higher than for patients requiring only 1 endoscopy (3%).[175] The median hospital costs for these patients were considerable, with costs for patients requiring over 1 endoscopy of $20,055, for patients requiring IRH of $34,730, and for patients requiring surgery of $47,589. According to the applicant, Hemospray is an alternative to IRH and surgery and the applicant

[168] Lau J, Barkun A, Fan D, Kuipers E, Yang Y, Chan F. Challenges in the management of acute peptic ulcer bleeding. Lancet 2013; 381: 2033–43.

[169] Mokhtare M, Bozorgi V, Agah S et al. Comparison of Glasgow-Blatchford score and full Rockall score systems to predict clinical outcomes in patients with upper gastrointestinal bleeding. Clin. Exp. Gastroenterol. 2016; 9: 337–43.

[170] Heller SJ, Tokar JL, Nguyen MT, et al. Management of bleeding GI tumors. Gastrointest Endosc 2010;72:817–24.

[171] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[172] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[173] Lau JY, Sung JJ, Lam YH, et al. Endoscopic retreatment compared with surgery in patients with recurrent bleeding after initial endoscopic control of bleeding ulcers. N Engl J Med 1999; 340: 751–756.

[174] Beggs AD, Dilworth MP, Powell SL, et al. A systematic review of transarterial embolization versus emergency surgery in treatment of major nonvariceal upper gastrointestinal bleeding. Clin Exp Gastroenterol 2014; 7: 93–104.

[175] Roy A, Kim M, Hawes R, Varadarajulu S. The clinical and cost implications of failed endoscopic hemostasis in gastroduodenal ulcer bleeding. UEG Journal 2017; 5(3): 359–364.

asserts it would avoid the costs associated with these procedures.

With respect to the newness criterion, the applicant for Hemospray was granted a FDA *de novo* classification request on May 7, 2018. The applicant stated revisions to the instructions for use were required by the FDA and therefore the device was not commercially available until July 1, 2018. The FDA has classified Hemospray as a Class II device for intraluminal gastrointestinal use. The applicant submitted a request for approval for a unique ICD–10–PCS code for the administration of Hemospray beginning in FY 2021 and was granted approval for the following procedure codes: XW0G886 (Introduction of mineral-based topical hemostatic agent into upper GI, via natural or artificial opening endoscopic, new technology group 6) and XW0H886 (Introduction of mineral-based topical hemostatic agent into lower GI, via natural or artificial opening endoscopic, new technology group 6).

According to information submitted by the applicant, Cook Medical recalled Hemospray ® Endoscopic Hemostat due to complaints received that the handle and/or activation knob on the device in some cases has cracked or broken when the device is activated and in some cases has caused the carbon dioxide cartridge to exit the handle. The applicant stated that Cook Medical received 1 report of a superficial laceration to the user's hand that required basic first aid; however, there have been no reports of laceration, infection, or permanent impairment of a body structure to users or to patients due to the carbon dioxide cartridge exiting the handle. The applicant stated that Cook Medical initiated an investigation to determine the appropriate corrective action(s) to prevent recurrence of this issue. According to the applicant, although the recall did restrict availability of the device, they wished to continue their application for new technology add-on payment as they believe the use of Hemospray significantly improves clinical outcomes for certain patient populations compared to currently available treatments.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. The applicant identified three treatment options currently available for the treatment of bleeding of the gastrointestinal system, which were thermal modalities, injection needles, and mechanical modalities. The applicant stated that thermal modalities are those endoscopic methods that treat gastrointestinal hemorrhage by means of bipolar electrocautery, hemostatic graspers, and argon plasma coagulation. These devices generate heat resulting in edema, coagulation of tissue protein, and contraction of vessels and indirect activation of the coagulation cascade. The applicant stated that injection needles treat gastrointestinal hemorrhage through the injection of various materials including epinephrine, saline, histoacryl, ethanolamine, and ethanol. This method achieves hemostasis by both mechanical tamponade and cytochemical mechanisms.[176] The applicant stated that mechanical modalities including hemostatic endoclips, detachable loop ligators and multi-band ligators control gastrointestinal hemorrhage by applying mechanical pressure to the bleeding site. The applicant claimed these treatment options (thermal modalities, injection needles, and mechanical modalities) are insufficient in achieving hemostasis as evidenced by rates of failed hemostasis of 8 to 15 percent.[177] The applicant stated that all the current treatments result in injury to the tissue, which in some cases can result in a worsening of the severity of the bleeding or perforation. Furthermore, it stated that with the exception of argon plasma coagulation, the current hemostatic modalities require precise targeting of the source of the bleed, which may limit their utility when diffuse or non-precise bleeding occurs. According to the applicant, the primary benefit of all endoscopic hemostasis procedures, including Hemospray, is the achievement of hemostasis without conversion to interventional radiology or surgery, both of which carry higher risk of mortality and morbidity.[178]

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the application asserted that Hemospray is a novel device in which the mechanism of action differs from alternative treatments by creating a diffuse mechanical barrier over the site of bleeding with a non-thermal, non-traumatic, noncontact modality.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant did not specifically comment. The applicant stated that cases involving the use of Hemospray would span a wide variety of MS–DRGs, but that the technology would most likely be used for cases in MS–DRGs 377, 378, and 379 (G.I. Hemorrhage with MCC, with CC, and without CC/MCC, respectively). We believe that cases involving the use of the technology would be assigned to the same MS–DRG as cases involving the current standard of care treatments.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, we noted that the applicant also did not comment specifically on this criterion. However, we noted that we believed that this technology would be used to treat the same or similar type of disease and the same or similar patient population as the current standard of care treatments.

Based on the applicant's statements as summarized previously, the applicant believed that Hemospray was not substantially similar to other currently available therapies and/or technologies and met the ''newness'' criterion. However, we stated in the proposed rule that we were concerned that the mechanism of action of Hemospray may be similar to existing endoscopic hemostatic treatments. Specifically, we noted that as described in literature provided by the applicant, technologies such as Ankaferd Bloodstopper and EndoClot Polysaccharide Hemostatic System appeared to utilize a similar mechanism of action as Hemospray to achieve hemostasis.[179] Based on the literature provided by the applicant, EndoClot, a device developed in California, USA, ''. . . consists of absorbable modified polymer . . . [which is] biocompatible, non-pyogenic, and starch-derived compound that rapidly absorbs water from serum and concentrates platelets, red blood cells, and coagulation proteins at the bleeding site to accelerate the clotting cascade.'' [180] EndoClot received 510(k) premarket notification January 18, 2017 and is indicated by the FDA to assist the delivery of a powdered hemostatic agent to the treatment site in endoscopic

[176] ASGE, The role of endoscopy in the management of acute non-variceal upper GI bleeding, Gastrointestinal Endoscopy. 2012; 75(6): 1132–1138.

[177] Lau J, Barkun A, Fan D, Kuipers E, Yang Y, Chan F. Challenges in the management of acute peptic ulcer bleeding. Lancet 2013; 381: 2033–43.

[178] Beggs AD, Dilworth MP, Powell SL, et al. A systematic review of transarterial embolization versus emergency surgery in treatment of major nonvariceal upper gastrointestinal bleeding. Clin Exp Gastroenterol 2014; 7: 93–104.

[179] Barkun, A., Moosavi, S., & Martel, M. (2013). Topical hemostatic agents: A systematic review with particular emphasis on endoscopic application in GI bleeding. Gastrointestinal Endoscopy, 77(5), 692–700.

[180] Ibid.

surgeries. Therefore, we were concerned with the similarity of this mechanism of action. Moreover, as previously noted, the applicant asserted generally it did not meet the substantial similarity criteria, but did not specifically address the second and third substantial similarity criteria. We believed that cases involving the use of the Hemospray would be assigned to the same MS–DRG as cases involving the current standard of-care treatments and that the technology would be used to treat the same or similar type of disease and the same or similar patient population as the current standard-of-care treatments. We invited public comments on whether Hemospray is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

Comment: The applicant reasserted that Hemospray meets the newness criterion because of the FDA de Novo classification, which according to the applicant confirms there is no comparable predicate hemostasis device cleared for use in the United States. The applicant stated that both the Ankaferd Blood Stopper (ABS) and EndoClot systems are not cleared for use in the United States with the latter only having clearance for the delivery system and for a product intended for submucosal injection.

In regard to the first substantial similarity criterion, the applicant stated that Hemospray has a different mechanism of action as compared to ABS and the EndoClot systems which are, according to the applicant, comprised of biologically active materials or absorbable polysaccharides. The applicant stated that ABS uses an active process related to proteins, via the formation of an encapsulated protein network that provides focal points for vital erythrocyte aggregation, that is substantially different from Hemospray. The applicant then stated with regard to EndoClot that the product produces a gelled matrix that adheres to and seals bleeding tissue; according to the applicant EndoClot substantially differs from Hemospray in its composition and properties that permit dissolution and degradation. Furthermore, the applicant stated that labeling in markets where EndoClot is commercially available limits its use to non-bleeding wounds within the GI tract, while Hemospray is indicated for active bleeding.

With regard to the second substantial similarity criterion, the applicant maintained that currently all control of GI bleeding no matter the treatment is typically grouped to MS–DRGs 377, 378, and 379.

With regard to the third substantial similarity criterion, the applicant stated that Hemospray will treat the same or similar type of disease and a similar patient population. They added that the unique features of the product differ substantially from other treatments and therefore, Hemospray meets the newness criterion.

Response: After consideration of the public comments we received and information submitted by the applicant in its application, we believe that while potential cases representing patients who may be eligible for treatment involving Hemospray would be assigned to the same MS–DRGs as cases representing patients who receive SOC treatment for a diagnosis of nonvariceal gastrointestinal bleeding, and that Hemospray is used to treat the same or similar type of disease (a diagnosis of nonvariceal gastrointestinal bleeding) and a similar patient population as currently available treatment options, we agree with the applicant that Hemospray does not use the same or similar mechanism of action as other technologies used for the treatment of nonvariceal gastrointestinal bleeding. We believe that Hemospray's mechanism of action, which creates a diffuse mechanical barrier over the site of bleeding with a non-thermal, non-traumatic, non-contact modality, is unique and distinct from other forms of treatment available in the U.S. for nonvariceal gastrointestinal bleeding and, therefore, we believe that Hemospray meets the newness criterion. We consider the beginning of the newness period to commence on the first date Hemospray was commercially available, July 1, 2018.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate the technology meets the cost criterion. The applicant asserted patients who would use Hemospray are identified by using a combination of one ICD–10–PCS procedure code and one ICD–10–CM diagnosis code. The applicant provided a list of 39 ICD–10–PCS procedure codes that included 21 Non O.R. digestive system procedures and 18 Extensive O.R. digestive system procedures. The applicant provided a list of 32 ICD–10–CM diagnosis codes that included 29 principal diagnoses in MS–DRGs 377, 378, and 379 (G.I. Hemorrhage with MCC, with CC, and without CC/MCC, respectively) and 3 principal diagnoses in MDC 06 (Diseases and Disorders of the Digestive System) across 10 MS–DRG classifications. The applicant extracted claims from the FY 2018 MedPAR final rule dataset based on the presence of one procedure and one diagnosis code in the list provided. The applicant stated MS–DRGs 377, 378, and 379 made up 3 of the top 4 MS–DRGs by volume and about 64 percent of cases were grouped to these 3 MS–DRGs. The applicant stated consequently they limited their analysis to the cases assigned to MS–DRGs 377, 378, and 379 and those claims that would be used for IPPS rate setting. The applicant identified a total of 40,012 cases.

The applicant first calculated a case weighted threshold of $46,568 based upon the dollar threshold for each MS–DRG grouping and the proportion of cases in each MS–DRG. The applicant then calculated the average charge per case. The applicant stated Hemospray may not replace other therapies occurring during an inpatient stay and therefore chose to not remove charges for the prior technology or technology being replaced. Next the applicant calculated the average standardized charge per case using the FY 2018 IPPS Final Rule Impact file. The 2-year inflation factor of 11.1% (1.11100) was obtained from the FY 2020 IPPS/LTCH PPS final rule and applied to the average standardized charge per case. To determine the charges for Hemospray, the applicant used the inverse of the FY 2020 IPPS/LTCH PPS final rule supplies and equipment national average CCR of 0.299, based on an assumption that hospitals would use the inverse of the national average CCR for supplies and equipment to mark-up charges, and therefore assumed an average charge for Hemospray of $8,361.20. The applicant calculated the final inflated average case-weighted standardized charge per case by adding the charges for the new technology to the inflated average standardized charge per case. The applicant determined a final inflated average case-weighted standardized charge per case of $60,193, which exceeds the average case-weighted threshold amount of $46,568. We invited public comments on whether Hemospray meets the cost criterion.

Comment: The applicant maintained that Hemospray meets the cost criterion as the inflated average case-weighted standardized charge per case of $60,193 exceeds the average case-weighted threshold amount of $46,568. The applicant stated that they did not remove the costs for other devices because some physicians may choose to use Hemospray in conjunction with endoscopic clips or thermal coagulation.

Response: We appreciate the applicant's comment in response to the

proposed rule. Based on the cost analysis as described previously and after consideration of public comments we received, we believe Hemospray meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Hemospray represents a substantial clinical improvement over existing technologies. According to the applicant, Hemospray is a topically applied mineral powder that offers a novel primary treatment option for endoscopic bleeding management, serves as an option for patients who fail conventional endoscopic treatments, and serves as an alternative to interventional radiology hemostasis (IRH) and surgery. Broadly, the applicant outlined two treatment areas in which it asserted Hemospray would provide a substantial clinical improvement: (1) As a primary treatment or a rescue treatment after the failure of a conventional method, and (2) for the treatment of malignant lesions.

The applicant provided eight articles specifically for the purpose of addressing the substantial clinical improvement criterion. Three articles are systematic reviews, three are prospective studies, and two are retrospective studies.

The first article provided by the applicant was a prospective single armed multicenter phase two safety and efficacy study performed in France.[181] From March 2013 to January 2015, 64 endoscopists in 20 centers enrolled 202 patients in the study in which Hemospray was used as either a first line treatment (46.5%) or as salvage therapy (53.5%) following the unsuccessful treatment with another method. The indication for Hemospray as a first-line therapy or salvage therapy was at the discretion of the endoscopist. Of the 202 patients the mean age was 68.9, 69.3 percent were male, and all patients were classified into four primary etiologic groups: Ulcers (37.1%), malignant lesions (30.2%), post-endoscopic bleeding (17.3%), and other (15.3%). Patients were further classified by the American Society of Anesthesiologist (ASA) physical status scores with 4.5 percent as a normal healthy patient, 24.3 percent as a patient with mild systemic disease, 46 percent as a patient with severe systemic disease, 22.8 percent as a patient with severe systemic disease that is a constant threat to life, and 2.5 percent as a moribund patient who is not expected to survive without an operation.[182] [183] Immediate hemostasis was achieved in 96.5 percent across all patients; among treatment subtypes immediate hemostasis was achieved in 96.8 percent of first-line treated patients and 96.3 percent of salvage therapy patients. At day 30 the overall rebleeding was 33.5 percent of 185 patients with cumulative incidences of 41.4 percent for ulcers, 37.7 percent for malignant lesions, 17.6 percent for post-endoscopic bleedings, and 25 percent for others. When Hemospray was used as a first-line treatment, rebleeding at day 30 occurred in 26.5 percent (22/83) of overall lesions, 30.8 percent of ulcers, 33.3 percent of malignant lesions, 13.6 percent of post-endoscopic bleedings, and 22.2 percent of other. When Hemospray was used as a salvage therapy, rebleeding at day 30 occurred in 39.2 percent (40/102) of overall lesions, 43.9 percent of ulcers, 50.0 percent of malignant lesions, 25.0 percent of post-endoscopic bleedings, and 26.3 percent for others. According to the article, the favorable hemostatic results seen from Hemospray are due to its threefold mechanism of action: Formation of a mechanical barrier; concentration of clotting factors at the bleeding site; and enhancement of clot formation.[184] No severe adverse events were noted; however, the authors note the potential for pain exists due to the use of carbon dioxide. Lastly, the authors stated that while Hemospray was found to reduce the need for radiological embolization and surgery as salvage therapies, it was not found to be better than other hemostatic methods in terms of preventing rebleeding of ulcers.

A second article provided by the applicant contained a systematic review of published Hemospray case data summarizing 17 human and 2 animal studies.[185] The authors do not provide the total number of articles reviewed but do provide search terms and engines used to conduct the review. The studies included in this review included 6 case reports and 13 case series taking place in North America, Europe, Hong Kong, and Egypt up until August 2014. A total of 234 cases were identified of which 28.2 percent involved gastric bleeding, 6.4 percent esophageal bleeding, 26.5 percent duodenal bleeding, 3.85 percent bleeding of the gastroesophageal junction, and 11 percent bleeding of the lower gastrointestinal tract. (We note it is unclear what form of bleeding the remaining 24.1 percent of cases addressed.) The mean size of the bleeding source was 37.4 mm ranging from 8 mm to 350 mm. Hemospray was used as a primary and sole treatment in 83 percent of cases while 17 percent of cases used Hemospray as a follow-up treatment. Hemospray achieved hemostasis in 88.5 percent of all reviewed cases. Within the 72 hour post-treatment period, rebleeding occurred in 16.2 percent of patients and 27.3 percent of animal models. The authors acknowledge the potential for rare adverse events such as embolism, intestinal obstruction, and allergic reaction, but state no procedure related adverse events were associated with Hemospray-.[186]

The applicant provided a third article consisting of an abstract from another systematic review article.[187] The abstract purports to cover a review of prospective, retrospective, and randomized control trials evaluating Hemospray as a rescue therapy. Eighty-five articles were initially identified and 23 were selected for review. Of those, 5 studies were selected which met the inclusion criteria of the analysis. The median age of patients was 69, 68 percent were male. The abstract concludes that when used as a rescue therapy after the failure of conventional endoscopic modalities, in nonvariceal gastrointestinal bleeding, Hemospray seems to have significantly higher rates of immediate hemostasis.

A fourth article provided by the applicant described a single-arm retrospective analytical study of 261 enrolled patients conducted at 21 hospitals in Spain.[188] The mean age was 67 years old, 69 percent of patients were male, and the overall technical success, defined as correct assembly and delivery of Hemospray to a bleeding lesion, was 97.7 percent (95.1%–

[181] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[182] Ibid.

[183] ASA House of Delegates/Executive Committee. (2014, October 15). *ASA Physical Status Classification System.* Retrieved from American Society of Anesthesiologists: *https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system.*

[184] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[185] Changela K, Papafragkakis H, Ofori E, et al. Hemostatic powder spray: a new method for managing gastrointestinal bleeding. Ther Adv Gastroenterol 2015; 8(3): 125–135.

[186] Ibid.

[187] Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: analyzing the efficacy of hemostatic nanopowder (TC–325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S–741.

[188] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

99.2%). The most common causes of bleeding in patients were peptic ulcer (28%), malignancy (18.4%), therapeutic endoscopy-related (17.6%), and surgical anastomosis (8.8%). Overall, 93.5 percent (89.5%–96%) of procedures achieved hemostasis. Recurrent bleeding, defined as (1) a new episode of bleeding symptoms, (2) a decrease in hemoglobin of >2 g/dL within 48 hours of an index endoscopy or > 3g/dL in 24 hours, or 3) direct visualization of active bleeding at the previously treated lesion on repeat endoscopy, had a cumulative incidence at 3 and 30 days of 16.1 percent (11.9%–21%) and 22.9 percent (17.8%–28.3%) respectively. The overall risk of Hemospray failure at 3 and 30 days was 21.1 percent (16.4%–26.2%) and 27.4 percent (22.1%–32.9%) respectively with no statistically significant differences (p = 0.07) between causes at 30 days (for example peptic ulcer, malignancy, anastomosis, therapeutic endoscopy-related, and other causes). With the use of multivariate analysis, spurting bleeding vs. nonspurting bleeding (subdistribution hazard ratio [sHR] 1.97 (1.24–3.13)), hypotension vs. normotensive (sHR 2.14 (1.22–3.75)), and the use of vasoactive drugs (sHR 1.80 (1.10–2.95)) were independently associated with Hemospray failure. The overall 30-day survival was 81.9 percent (76.5%–86.1%) with 46 patients dying during follow-up and 22 experiencing bleeding related deaths; 20 patients (7.6%) with intraprocedural hemostasis died before day 30. The authors indicated the majority of Hemospray failures occurred within the first 3 days and the rate of immediate hemostasis was similar to literature reports of intraprocedural success rates of over 90 percent. The authors stated that the hemostatic powder of Hemospray is eliminated from the GI tract as early as 24 hours after use, which could explain the wide ranging recurrent bleeding percentage. The authors reported that importantly, adverse events are rare, but cases of abdominal distension, visceral perforation, transient biliary obstruction, and splenic infarct have been reported; one patient involved in this study experienced an esophageal perforation without a definitive causal relationship.

A fifth article provided by the applicant described a single-arm multicenter prospective registry involving 314 patients in Europe which collected data on days 0, 1, 3, 7, 14, and 30 after endotherapy with Hemospray.[189] The outcomes of interest in this study were immediate endoscopic hemostasis (observed cessation of bleeding within 5 minutes post Hemospray application) with secondary outcomes of rebleeding immediately following treatment and during follow-up, 7 and 30 day all-cause mortality, and adverse events. The sample was 74 percent male with a median age of 71 with the most common pathologies of peptic ulcer (53%), malignancy (16%), post-endoscopic bleeding (16%), bleeding from severe inflammation (11%), esophageal variceal bleeding (2.5%), and cases with no obvious cause (1.6%). The median baseline Blatchford score (BS) and RS were 11 and 7 respectively. The BS ranges from 0 to 23 with higher scores indicating increasing risk for required endoscopic intervention and is based upon the blood urea nitrogen, hemoglobin, systolic blood pressure, pulse, presence of melena, syncope, hepatic disease, and/or cardiac failure.[190] The RS ranges from 0 to 11 with higher scores indicating worse potential outcomes and is based upon age, presence of shock, comorbidity, diagnosis, and endoscopic stigmata of recent hemorrhage.[191] Immediate hemostasis was achieved in 89.5 percent of patients following the use of Hemospray; only the BS was found to have a positive correlation with treatment failure in multivariate analysis (OR 1.21 (1.10–1.34)). Rebleeding occurred in 10.3 percent of patients who achieved immediate hemostasis again with only the BS having a positive correlation with rebleeding (OR: 1.13 (1.03–1.25)). At 30 days the all-cause mortality was 20.1 percent with 78 percent of these patients having achieved immediate endoscopic hemostasis and a cause of death resulting from the progression of other comorbidities. A subgroup analysis of treatment type (monotherapy, combination therapy, and rescue therapy groups) was performed showing no statistically significant difference in immediate hemostasis across groups (92.4 percent, 88.7 percent, and 85.5 percent respectively). Higher all-cause mortality rates at 30 days were highest in the monotherapy group (25.4%, p=0.04) as compared to all other groups. According to the authors, in comparison to major recent studies, they were able to show lower rebleeding rates overall and in all subgroups despite the high-risk population.[192] The authors further note limitations in that the inclusion of patients was nonconsecutive and at the discretion of the endoscopist, at the time of the endoscopy, which allows for the potential introduction of selection bias which may have affected these study results.

The fifth article also described the utility of Hemospray in the treatment of malignant lesions. According to the applicant, malignant lesions pose a significant clinical challenge as successful hemostasis rates are as low as 40 percent with high recurrent bleeding over 50 percent within 1 month following standard treatments.[193] [194] The applicant added that bleeding from tumors is often diffuse and consists of friable mucosa decreasing the utility of traditional treatments (for example, ligation, cautery). From the fifth article, the applicant noted that 50 patients were treated for malignant bleeding with overall immediate hemostasis in 94 percent of patients.[195] Of the 50 patients, 33 were treated with Hemospray alone, 11 were treated with Hemospray as the final treatment, and 4 were treated with Hemospray as rescue therapy of which 100 percent, 84.6 percent and 75 percent experienced immediate hemostasis respectively.[196] Similarly, from the first discussed article, the applicant noted that among malignant bleeding patients, 95.1 percent achieved immediate hemostasis with lower rebleeding rates at 8 days when Hemospray was used as a primary treatment as compared to when used as a rescue therapy (17.1 percent vs. 46.7 percent respectively).[197] The applicant concluded that Hemospray may provide an advantage as a primary treatment to patients with malignant bleeding.

A sixth article provided by the applicant consisted of a systematic

[189] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[190] Saltzman, J. (2019, October). Approach to acute upper gastrointestinal bleeding in adults. (M. Feldman, Editor) Retrieved from UpToDate: *https://www.uptodate.com/contents/approach-to-acute-upper-gastrointestinal-bleeding-in-adults*

[191] Ibid.

[192] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[193] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[194] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[195] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[196] Ibid.

[197] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

review from January 1950 to August 2014 concerning all available powdered topical hemostatic agents.[198] Of an initial 3,799 articles, 105 were initially reviewed and after excluding nonendoscopic data, review articles, in vitro studies, and animal models 61 articles were ultimately included in the study. Three primary hemostatic agents were identified in this review, the Ankaferd Blood Stopper (ABS), Hemospray, and EndoClot. The applicant noted the authors of this article identified 131 high risk patients treated with Hemospray, of which 28 had tumor bleeding. According to the applicant, all 28 patients achieved immediate hemostasis with 25 percent experiencing rebleeding at 7-day follow-up. The overall immediate hemostasis in this particular study was 91.6 percent and 7-day rebleeding was 25.8 percent among high-risk rebleeding patients.[199]

The applicant provided a seventh article which consisted of a journal pre-proof article detailing a 1:1 randomized control trial of 20 patients treated with Hemospray versus the standard of care (for example, thermal and injection therapies) in the treatment of malignant gastrointestinal bleeding.[200] The goals of this pilot study were to determine the feasibility of a definitive trial. The primary outcome of the study was immediate hemostasis (absence of bleeding after 3 minutes) with secondary outcomes of recurrent bleeding at days 1, 3, 30, 90, and 180 and adverse events at days 1, 30, and 180. The mean age of patients was 67.2, 75 percent were male, and on average patients presented with 2.9 ± 1.7 comorbidities. All patients had active bleeding at endoscopy and the majority of patients had an ASA score of 2 (45%) or 3 (40%). Immediate hemostasis was achieved in 90 percent of Hemospray patients and 40 percent of standard of care patients (5 injection alone, 3 thermal, 1 injection with clips, and 1 unknown). Of those patients in the control group, 83.3 percent crossed over to the Hemospray treatment. One patient died while being treated with Hemospray from exsanguination; post-mortem examination demonstrated that bleeding was caused by rupture of a malignant inferior mesenteric artery aneurysm. Overall, 86.7 percent of patients treated with Hemospray initially or as crossover treatment achieved hemostasis. Recurrent bleeding was lower in the Hemospray group (20%) as compared to the control group (60%) at 180 days. Forty percent of the treated group received blood transfusions as compared to 70 percent of the control group. The overall length of stay was 14.6 days among treated patients as compared to 9.4 in the control group. Mortality at 180 days was 80 percent in both the treated and control groups. The authors noted the potential for operator bias in the use of Hemospray prior to switching to another method when persistent bleeding exists. Lastly, the authors noted that while they did not occur during this study, there are concerns around the risks of perforation, obstruction, and systemic embolization with the use of Hemospray.

An eighth article provided by the applicant described a single-arm multicenter retrospective study from 2011 to 2016 involving 88 patients who bled as a result of either a primary GI tumor or metastases to the GI tract.[201] In this study the authors define immediate hemostasis as no further bleeding at least one minute after treatment with Hemospray and recurrent bleeding was suspected if one of seven criteria were met: (1) Hematemesis or bloody nasogastric tube >6 hours after endoscopy; (2) melena after normalization of stool color; (3) hematochezia after normalization of stool color or melena; (4) development of tachycardia or hypotension after >1 hour of vital sign stability without other cause; (5) decrease in hemoglobin level greater than or equal to 3 hours apart; (6) tachycardia or hypotension that does not resolve within 8 hours after index endoscopy; or (7) persistent decreasing hemoglobin of >3 g/dL in 24 hours associated with melena or hematochezia). The sample for this study consisted of 88 patients (with a mean age of 65 years old and 70.5 percent male) of which 33.3 percent possessed no co morbid illness, and 25 percent were on current antiplatelet/anticoagulant medication. The mean BS was 8.7 plus or minus 3.7 with a range from 0 to 18. Overall, 72.7 percent of patients had a stage 4 adenocarcinoma, squamous cell carcinoma, or lymphoma. Immediate hemostasis was achieved in 97.7 percent of patients. Recurrent bleeding occurred among 13 of 86 (15%) and 1 of 53 (1.9%) at 3 and 30 days, respectively. A total of 25 patients (28.4%) died during the 30-day follow up period. Overall, 27.3 percent of patients re-bled within 30 days after treatment of which half were within 3 days. Using multivariate analysis, the authors found that patients with good performance status, no end-stage cancer, or receiving any combination of definitive hemostasis treatment modalities had significantly greater survival. The authors acknowledged the recurrent bleeding rate post Hemospray treatment at 30 days of 38 percent is comparable with that seen in sole conventional hemostatic techniques (40–50%) and state this implies that the long-term effect of Hemospray does not differ from conventional techniques and remains unsatisfactory for upper GI tumor-related bleeding. However, they state that Hemospray is more predictably effective in providing initial hemostasis for tumor-related GI bleeding than conventional methods as SOC methods provide variable immediate hemostasis rates of 31 to 93 percent while Hemospray had a 97.7% success rate in this study. They further conclude that though Hemospray may provide only a temporary hemostatic effect in this group of patients, its strong efficacy in the short-term allows patients to subsequently receive definitive hemostatic treatment that may translate into higher 6-month survival rates.

Ultimately, the applicant concluded nonvariceal gastrointestinal bleeding is associated with significant morbidity and mortality in older patients with multiple co-morbid conditions. Inability to achieve hemostasis and early rebleeding are associated with increased cost and greater resource utilization. According to the applicant, patients with bleeding from malignant lesions have few options that can provide immediate hemostasis without further disrupting fragile mucosal tissue and worsening the active bleed. The applicant asserted Hemospray is an effective agent that provides immediate hemostasis in patients with GI bleeding as part of multimodality treatment, as well as when used to rescue patients who have failed more conventional endoscopic modalities. Furthermore, the applicant stated that in patients with malignant bleeding in the GI tract, Hemospray provides a high rate of immediate hemostasis and fewer recurrent bleeding episodes, which in combination with definitive cancer treatment may lead to improvements in long term survival. Lastly, the applicant asserted Hemospray is an important

[198] Chen Y–I, Barkun A. Hemostatic powders in gastrointestinal bleeding, a systematic review. Gastrointest Endoscopy Clin N Am 2015; 25: 535–552.

[199] Ibid.

[200] Chen Y–I, Wyse J, Lu Y, Martel M, Barkun AN, TC–325 hemostatic powder versus current standard of care in managing malignant GI bleeding: A pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: *https://doi.org/10.1016/j.gie.2019.08.005*.

[201] Pittayanon R, Rerknimitr R, Barkun A. Prognostic factors affecting outcomes in patients with malignana GI bleeding treated with a novel endoscopically delivered hemostatic powder. Gastrointest Endosc 2018; 87:991–1002.

new technology that permits immediate and long-term hemostasis in GI bleeding cases where standard of care treatment with clip ligation or cautery are not effective.

We noted in the proposed rule that the majority of studies provided lack a comparator when assessing the effectiveness of Hemospray. Three of the articles provided were systematic reviews of the literature. We noted that while we found these articles helpful in establishing a background for the use of Hemospray, we were concerned that they may not provide strong evidence of substantial clinical improvement. Four studies appeared to be single-armed studies assessing the efficacy of Hemospray in the patient setting. We stated that in all of these articles, comparisons were made between Hemospray and standard of care treatments; however, without the ability to control for factors such as study design, patient characteristics, etc., it was difficult to determine if any differences seen result from Hemospray or confounding variables. Furthermore, within the retrospective and prospective studies lacking a control subset, some level of selection bias appeared to potentially be introduced in that providers may be allowed to select the manner and order in which patients are treated, thereby potentially influencing outcomes seen in these studies.

Additionally, one randomized control trial provided by the applicant appeared to be in the process of peer-review and was not yet published. Furthermore, we noted that this article was written as a feasibility study for a potentially larger randomized control trial and contains a sample of only 20 patients. This small sample size left us concerned that the results are not representative of any larger population. Lastly, as described, we were concerned the control group can receive one of multiple treatments which lack a clear designation methodology beyond physician choice. For instance, 50 percent of the control patients received injection therapy alone, which according to the literature provided by the applicant was not an acceptable treatment for endoscopic bleeding. Accordingly, it was not clear whether performance seen in the treated group as compared to the control group is due to Hemospray itself or due to confounding factors.

Third, we were concerned with the samples chosen in many of the studies presented. Firstly, we noted that the Medicare population is a diverse group of men and women. Many of the samples provided by the applicant were overwhelmingly male. Secondly, many of the studies provided were performed in European and other settings outside of the United States. We were therefore concerned that the samples chosen within the literature provided may not represent the Medicare population.

Lastly, we were concerned about the potential for adverse events resulting from Hemospray. It was unclear from the literature provided by the applicant what the likelihood of these events were and whether or not an evaluation for the safety of Hemospray was performed. About one-third of the articles submitted specifically addressed adverse events with Hemospray. However, the evaluation of adverse events was limited and most of the patients in the studies died of disease progression. A few of the provided articles stated the potential for severe adverse reactions (for example, abdominal distension, visceral perforation, biliary obstruction, splenic infarct). Specifically, one article [202] recorded adverse events related to Hemospray, including abdominal distention and esophageal perforation. We invited public comments on whether Hemospray meets the substantial clinical improvement criterion.

Comment: According to the applicant, a recently published study randomized Hemospray against dual therapy as first treatment and demonstrated Hemospray is a viable alternative to dual therapy.[203] This multicenter non-inferiority randomized controlled trial assigned patients with active non-variceal upper GI bleeding to receive either Hemospray or standard dual modality treatment. A total of 224 patients were randomized. With intention-to-treat analysis, the re-bleeding free probability over 30 days was 89.8% in the TC–325 group and 81.1% in the standard treatment group (difference in proportions, 95% CI; 8.7%, −1.3%, 18,7%). There were fewer failures in the control of bleeding during index endoscopy with the use of Hemospray (3 vs. 11, OR, 95% CI, 3.88, 1.05–14.32), although 30-day re-bleeding and mortality was not different between groups.

The applicant agreed with CMS that the use of single arm and retrospective studies potentially suffer from selection bias. The applicant asserted that while this bias is inevitable, the retrospective studies specifically exclude those cases successfully treated with conventional dual therapy. According to the applicant, this therefore ensured the bias was toward the patients with the highest risk of treatment failure, morbidity, and mortality, and representing the most challenging hemostasis cases. The applicant stated that in both the Rodriguez de Santiago et al. and Alzoubaidi et al. articles, there was an overall treatment success with no rebleeding in 70% of cases where Hemospray was used after all other conventional treatments failed.

In response to CMS' concerns about the randomized control trial (RCT), the applicant stated that the study evaluated patients with bleeding from malignant lesions and has now been published. According to the applicant, the comparator treatment used in this study, injection only, is consistent with the 2016 guidelines of the European Society of Gastrointestinal Endoscopy for the treatment of bleeding from upper GI malignancies which recommends, ''endoscopic monotherapy with epinephrine injection . . . or saline injection . . .''.[204] The applicant stated that while the study was a small sample size pilot study, the results are representative of the general population with malignant GI bleeding. Further, the applicant stated that in the study by Alzoubaidi et al. 50 patients with symptomatic bleeding secondary to malignancy were treated. Hemospray monotherapy was the most common mode of treatment (33/50 = 66 percent) with a hemostasis rate of 100 percent. In the remaining patients, Hemospray was used in combination with conventional methods or as a rescue, with a lower aggregate rate of immediate hemostasis.

In response to CMS' concerns about the study samples presented, the applicant acknowledged that the majority of data came from outside of the United States due to commercial availability. The applicant stated that the FDA considered the outside of the United States data to be representative of the US population when granting a de novo classification request for the product. In response to CMS' concern that the provided literature showed a predominance of males, the applicant stated that the 2016 Healthcare Cost and Utilization Project (HCUP) showed that 60% of patients that underwent endoscopic control of bleeding were male. Lastly, the applicant stated that

[202] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

[203] AB14 GASTROINTESTINAL ENDOSCOPY Volume 91, No. 6S: 2020. #98 by Lau et al.

[204] Gralnek IM, Dumonceau J–M, Kuipers EJ. Diagnosis and management of nonvariceal upper gastrointestinal hemorrhage: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy 2015; 47: 1–46

from the three studies [205] [206] [207] representing 777 patients, the median or average age ranged from 67–71 which they believed to be representative of the Medicare population.

In response to CMS' concerns about potential adverse events, the applicant stated that the FDA determined the product is safe and effective for its intended use and has an acceptable risk/benefit ratio when it granted de Novo classification request and authorization to market in the United States. According to the applicant, any procedure is associated with risks. The applicant stated that they understand the potential risks associated with Hemospray and that they clearly labeled their product with such information. The applicant also conducts physician training to ensure physicians understand the risks and select patients who they believe would benefit most from Hemospray. In addition, the applicant conveyed that they diligently monitor reported complaints or complications related to a device once it is in the real world. According to the applicant, the same will be done with Hemospray and if the risk ratio increases to an unacceptable level; the applicant will take appropriate steps to correct it. According to the applicant, these are the standard processes with any device and the applicant does not see a reason to divert from these processes for Hemospray.

The applicant acknowledged that it had initiated a voluntary recall of Hemospray due to complaints received that the handle and/or activation knob on the device in some cases had cracked or broken when the device was activated and in some cases had caused the carbon dioxide cartridge to exit the handle. According to the applicant, as of June 10, 2020, the FDA cleared Hemospray to return to the market (K200972) after the applicant sufficiently addressed the issue that led to the cartridge exiting the handle. As such, Hemospray will return to the US market in July 2020.

One commenter stated that they frequently use Hemospray and believe it is irreplaceable in the role of controlling tumor bleeding. The commenter added that Hemospray has a critical role in rescue bleeding in cases that preclude contact hemostatic methods due to the risk of perforation. They stated that Hemospray's ability to buy time to resuscitate during challenging bleeding cases is the most understated benefit of the device. Lastly, the commenter stated that there are currently no hemostatic powder alternatives on the market in the United States.

Response: We appreciate the commenters' input in response to the concerns discussed in the proposed rule regarding the substantial clinical improvement criterion. We agree with the applicant that the control therapy in the RCT, injection only as compared to dual therapy, was appropriate based on the 2016 guidelines of the European Society of Gastrointestinal Endoscopy for the treatment of bleeding from upper GI malignancies. In the commenter's response to CMS regarding potential selection bias in single arm and retrospective studies, the applicant stated that based on the study design, any potential bias introduced was toward the patients with the highest risk of negative outcomes. We appreciate the applicant's response to our concerns and agree that this potential bias is no longer a concern. Regarding the applicant's comment on study samples, we agree with the applicant that these samples are adequately representative of the Medicare population. We also appreciate the comment response to the potential for adverse events. We will continue to monitor available data for Hemospray in regard to any potential risk of adverse events. Finally, we appreciate the applicant's update on the status of their voluntary recall of the Hemospray system.

While we acknowledge the limitations of some of the data, we believe that Hemospray represents a substantial clinical improvement for the treatment of gastrointestinal bleeding for the following reasons. We believe that given the results from the RCT trials and the single-armed studies Hemospray provides a treatment benefit particularly for those with bleeding from GI malignancies. We also see the clinical importance of Hemospray as an alternative to invasive treatments traditionally used as salvage therapy. Lastly, we note that Hemospray provides treatment for bleeding without requiring tissue trauma or precise targeting.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that Hemospray meets the criteria for approval of the new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2021. Cases involving the use of Hemospray that are eligible for new technology add-on payments will be identified by procedure codes XW0G886 (Introduction of mineral-based topical hemostatic agent into upper GI, via natural or artificial opening endoscopic, new technology group 6) and XW0H886 (Introduction of mineral-based topical hemostatic agent into lower GI, via natural or artificial opening endoscopic, new technology group 6).

In its application, the applicant estimated that the cost of Hemospray is $2,500.00 per patient. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of Hemospray is $1,625.00 for FY 2021.

h. IMFINZI® (durvalumab) and TECENTRIQ® (atezolizumab)

Two manufacturers, AstraZeneca PLC and Genentech, Inc., submitted separate applications for new technology add-on payments for FY 2021 for IMFINZI® (durvalumab) and TECENTRIQ® (atezolizumab), respectively. Both of these technologies are programmed death-ligand 1 (PD–L1) blocking antibodies used for the treatment of patients with extensive-stage small cell lung cancer (ES–SCLC).[208] In the proposed rule, we discussed these applications as two separate technologies. After further consideration and as discussed below, we believe IMFINZI® and TECENTRIQ® are substantially similar to each other and that it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. We refer the reader below for a complete discussion regarding our analysis of the substantial similarity of IMFINZI® and TECENTRIQ®.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32631) we noted, and as summarized in the following table, the FDA initially approved IMFINZI® on May 1, 2017 for the indicated treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease

[205] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[206] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

[207] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[208] TECENTRIQ (atezolizumab) [prescribing information]. San Francisco, CA: Genentech, Inc., 2019.

progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy. The FDA subsequently approved IMFINZI® on February 16, 2018 for a second indication, treatment of patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. IMFINZI® in combination with etoposide and either carboplatin or cisplatin was approved by the FDA as first-line treatment of patients with extensive-stage small cell lung cancer (ES–SCLC) on March 27, 2020, the indication for which the applicant is seeking new technology add-on payments.[209]With regard to TECENTRIQ®, and as summarized in the following table, the applicant stated TECENTRIQ® was initially approved by FDA on May 18, 2016, for treatment of patients with locally advanced or metastatic urothelial carcinoma,[210] and subsequently for patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy on October 18, 2016; [211] for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations on December 6, 2018; [212] and for metastatic triple negative breast cancer on March 8, 2019.[213]

TECENTRIQ® received FDA approval on March 18, 2019 in combination with carboplatin and etoposide for the first-line treatment of adult patients with ES–SCLC, the indication for which the applicant is seeking new technology add-on payments. The applicant stated that TECENTRIQ® is the first cancer immunotherapy to be approved in the first-line treatment of ES–SCLC.[214] The applicant stated that the National Comprehensive Cancer Network (NCCN) recommends TECENTRIQ® + carboplatin + etoposide as the only category 1 preferred initial treatment for patients with ES–SCLC.[215]

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[209] *https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-extensive-stage-small-cell-lung-cancer.*

[210] U.S. Department of Health and Human Services. BLA Accelerated Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/761034Orig1s000ltr.pdf.* Accessed August 9, 2019.

[211] U.S. Department of Health and Human Services. BLA Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/761041Orig1s000ltr.pdf.* Accessed August 9, 2019.

[212] U.S. Department of Health and Human Services. Supplement Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/761034Orig1s009ltr_REPLACEMENT.pdf.* Accessed August 9, 2019.

[213] U.S. Department of Health and Human Services. Accelerated Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761034Orig1s018ltr.pdf.* Accessed August 9, 2019.

[214] U.S. Department of Health and Human Services. Supplemental Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761034Orig1s019ltr.pdf.* Accessed August 9, 2019.

[215] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer Version 2.2019. *https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.* Accessed August 16, 2019.

COMPARISON OF INDICATION AND FDA APPROVAL FOR IMFINZI® AND TECENTRIQ®

FY 2021 Applicant Technology Name	Description of Indication for which New Technology Add-on Payments Are Being Requested	FDA Approval Status
IMFINZI® (AstraZeneca PLC)	In combination with etoposide and either carboplatin or cisplatin, first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).	FDA approval received 3/27/2020
TECENTRIQ® (Genentech, Inc.)	In combination with carboplatin and etoposide, first-line treatment of adult patients with ES-SCLC.	FDA approval received 3/18/2019
Technology Approved for Other Indications	Description of Other Indication	FDA Approval of Other Indication
IMFINZI® (AstraZeneca PLC)	Treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy.	FDA approval received 5/1/2017
	Treatment of patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy	FDA approval received 2/16/2018
TECENTRIQ® (Genentech, Inc.)	Treatment of patients with locally advanced or metastatic urothelial carcinoma, and subsequently for patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy.	FDA approval received 5/18/2016
	Treatment of patients with metastatic non-small cell lung cancer who have disease progression during or following platinum-containing chemotherapy.	FDA approval received 10/18/2016
	First-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.	FDA approval received 12/6/2018
	Metastatic triple negative breast cancer.	FDA approval received 3/8/2019

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In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32663), we noted that the applicant for TECENTRIQ® submitted a request for a unique ICD–

10–PCS code for TECENTRIQ® beginning in FY 2021. The following ICD–10–PCS codes, effective October 1, 2020, were approved for procedures involving the administration of TECENTRIQ®: XW033D6 (Introduction of atezolizumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6) and XW043D6 (Introduction of atezolizumab antineoplastic into central vein, percutaneous approach, new technology group 6). In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32632), we noted that the applicant for IMFINZI® submitted a request for a unique ICD–10–PCS code for IMFINZI® beginning in FY 2021. The following ICD–10–PCS codes, effective October 1, 2020, were approved for procedures involving the administration of IMFINZI®: XW03336 (Introduction of durvalumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6) and XW04336 (Introduction of durvalumab antineoplastic into central vein, percutaneous approach, new technology group 6).

According to the applicant for TECENTRIQ®, lung cancer is the second most commonly diagnosed cancer and the leading cause of cancer-related death among men and women in the United States.[216] SCLC is a high-grade neuroendocrine tumor comprising small cells with minimal cytoplasm, poorly defined cell borders, and either no nucleoli or unremarkable nucleoli.[217] [218] The most aggressive of all lung cancers, it accounts for about 10–15 percent of lung cancer cases.[219] Key characteristics of SCLC include its rapid doubling time and the early development of widespread metastases.[220] [221] About 72 percent of SCLC cases are diagnosed at the extensive stage, which is associated with a 5-year survival rate of 2.9 percent.[222] [223] According to the applicant for IMFINZI®, 75 percent of patients are diagnosed in the late/metastatic stage described as ES–SCLC and are considered incurable, with a median overall survival of 9–11 months with standard of care (SOC).[224] [225] The median overall survival for ES–SCLC has remained the same for the past 20 years with essentially no improvements or new therapies.[226]

According to the applicant for TECENTRIQ®, the current SOC treatment for ES–SCLC is a combination of etoposide, which is FDA-approved in SCLC only in combination with cisplatin, and carboplatin, which is used in preference to cisplatin for toxicity reasons, despite being off-label.[227] Although ES–SCLC is highly sensitive to platinum/etoposide in the first-line setting with response rates of 50–60 percent, the majority of patients will relapse within the first year of treatment, with a median progression-free survival (PFS) of 4–6 months.[228] The applicant for IMFINZI® also asserted that overall, responses to SOC are short-lived and long-term outcomes remain poor.[229]

The applicant for IMFINZI® further stated that diagnosis often occurs at later stages and SCLC patients may be sicker at the time of diagnosis, presenting with comorbidities.[230] [231] For these reasons, the applicant asserted that a significant number of patients present and are diagnosed in the hospital inpatient setting. According to the applicant, ES–SCLC is very responsive to chemotherapy treatment, with response rates to platinum/etoposide ranging from 44 percent to 78 percent,[232] and given the severity of symptoms, it is recommended to initiate treatment within two weeks of diagnosis.[233] According to the applicant, many patients have a clinical response and improvement of symptoms with the initiation of platinum/etoposide, confirming the clinical observation that many SCLCs are highly sensitive to platinum/etoposide in the first-line setting.[234] According to the applicant for TECENTRIQ®, despite SOC chemotherapy regimens using etoposide and carboplatin, the majority of patients with ES–SCLC will experience recurrence within 1 year. Median progression-free survival (PFS) and overall survival (OS) rates are 2 months and 10 months, respectively, after initial chemotherapy.[235] [236] [237]

According to the applicant for TECENTRIQ®, progress in the treatment of ES–SCLC has been limited. Over the past 40 years, the 2-year OS has increased from 3.4 percent to 5.6 percent, and the median OS has remained at about 10 months since the 1980s.[238] [239] [240] One paper submitted by

[216] American Cancer Society. Lung Cancer Prevention and Early Detection. American Cancer Society. *https://www.cancer.org/cancer/lung-cancer/prevention-and-early-detection.html.* Accessed October 3, 2019.

[217] Meerbeeck, J.P.V., Fennell, D.A., Ruysscher, D.K.D, ''Small-cell Lung Cancer,'' *The Lancet,* 2011, 378(9804), pp.1741–1755, doi:10.1016/s0140–6736(11):60165–7.

[218] Kalemkerian, G., ''Small Cell Lung Cancer,'' *Seminars in Respiratory and Critical Care Medicine,* 2016, 37(05) pp.783–796, doi:10.1055/s-0036-1592116.

[219] WebMD, LLC. Types of Lung Cancer. *https://www.webmd.com/lung-cancer/lung-cancer-types#1.* Accessed August 15, 2019.

[220] Harris, K., Khachaturova, I., Azab, B., et al., ''Small Cell Lung Cancer Doubling Time and its Effect on Clinical Presentation: a Concise Review,'' *Sage Journals,* 2012, 6, pp.199–203, doi:10.4137/CMO.S9633.

[221] Pietanza, M.C., Averett, L., Minna, J., Rudin, C.M., ''Small Cell Lung Cancer: Will Recent Progress Lead to Improved Outcomes?,'' *Clinical Cancer Research,* 2015, (21), pp. 2244–2255, doi: 10.1158/1078–0432.CCR–14–2958.

[222] American Lung Association. Trends in Lung Cancer Morbidity and Mortality. *https://www.lung.org/assets/documents/research/lc-trend-report.pdf.* Accessed August 15, 2019.

[223] Noone, A.M., Howlader, N., Krapcho, M., et al., SEER Cancer Statistics Review, 1975–2015, based on November 2017 SEER data submission, posted to the SEER website, April 2018. Bethesda, MD: National Cancer Institute. 2018; *https://seer.cancer.gov/csr/1975_2015/results_merged/sect_15_lung_bronchus.pdf.* Accessed September 23, 2019.

[224] Sabari, J.K., Lok, B.H., Laird, J.H., et al., ''Unravelling the biology of SCLC: Implications for therapy,'' *Nature Reviews Clinical Oncology,* 2017, 14(9), pp. 549–561.

[225] Farago, A..F., Keane F.K., ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7, pp. 69–79.

[226] Ibid.

[227] UpToDate, Inc. ES-Small Cell Lung Cancer: Initial Management. *https://www.uptodate.com/contents/extensive-stage-small-cell-lung-cancer-initial-management.* Accessed July 26, 2019.

[228] Hurwitz, J.L., McCoy, F., Scullin, P., et al., ''New advances in the second-line treatment of small cell lung cancer,'' *Oncologist,* 2009, 14(10), pp. 986–994.

[229] Haque, N., Raza, A., McGoey, R., et al., ''Small cell lung cancer: time to diagnosis and treatment,'' *Southern Medical Journal,* 2012, 105(8), pp. 418–423.

[230] Bennett, B.M., Wells, J.R., Panter, C., et al., ''The humanistic burden of small cell lung cancer (SCLC): A systematic review of health-related quality of life (HRQoL) literature,'' *Frontiers in Pharmacology,* 2017, 8, p. 339.

[231] Aarts, M.J., Aerts, J.G., van den Borne, B.E., et al., ''Comorbidity in patients with small-cell lung cancer: Trends and prognostic impact,'' *Clinical Lung Cancer,* 2015, 16(4), pp. 282–291.

[232] Farago, A.F., Keane, F.K, ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7, pp. 69–79.

[233] Haque, N., Raza, A., McGoey, R., et al., ''Small cell lung cancer: Time to diagnosis and treatment,'' *Southern Medical Journal,* 2012, 105(8), pp. 418–423.

[234] Ibid.

[235] Kalemkerian, G., ''Small Cell Lung Cancer,'' *Seminars in Respiratory and Critical Care Medicine,* 2016, 37(05):783–796. doi:10.1055/s-0036–1592116.

[236] Gadgeel, S.M., Pennell, N.A., Fidler, M.J., et al., ''Phase II Study of Maintenance Pembrolizumab in Patients with ES-Small Cell Lung Cancer (SCLC),'' *Journal of Thoracic Oncology,* 2018, 13(9), pp. 1393–1399. doi:10.1016/j.jtho.2018.05.002.

[237] Rossi, A., ''Relapsed Small-Cell Lung Cancer: Platinum Re-Challenge Or Not,'' *Journal of Thoracic Disease,* 2016, 8(9), pp. 2360–2364, doi:10.21037/jtd.2016.09.28.

[238] Kalemkerian, G., ''Small Cell Lung Cancer,'' *Seminars in Respiratory and Critical Care Medicine,* 2016, 37(05), pp. 783–796, doi:10.1055/s-0036-1592116.

[239] Evans, W.K., Shepherd, F.A., Feld, R., Osoba, D., Dang, P., Deboer, G., ''VP–16 and Cisplatin as First-Line Therapy for Small-Cell Lung Cancer,'' *Journal of Clinical Oncology,* 1985, 3(11), pp. 1471–1477, doi:10.1200/jco.1985.3.11.1471.

[240] Boni, C., Cocconi, G., Bisagni, G., Ceci, G., Peracchia, G., Cisplatin and Etoposide (VP–16) as a Single Regimen for Small Cell Lung Cancer. A

Continued

the applicant noted that more than 40 phase III trials evaluating other regimens in SCLC have failed since 1970.[241]

As stated earlier and for the reasons discussed further later in this section, we believe that IMFINZI® and TECENTRIQ® are substantially similar to each other such that it is appropriate to analyze these two applications as one technology for purposes of new technology add-on payments, in accordance with our policy. Below we discuss the information provided by the applicants, as summarized in the proposed rule, regarding whether IMFINZI® and TECENTRIQ® are substantially similar to existing technologies prior to their approval by the FDA and their release onto the U.S. market. As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant for TECENTRIQ® asserted that the mechanism of action of ES–SCLC is not the same as or similar to an existing technology. The applicant described TECENTRIQ® as a programmed PD–L1 blocking antibody, and as the first and only blocking antibody to target the PD–L1/PD–1 pathway that is FDA-approved for the treatment of ES–SCLC. The applicant explained that PD–L1 is a protein expressed on the surface of cancer cells, which allows them to inactivate the T-cells of the patient's immune system which would normally attack the cancer cells. The applicant asserted that TECENTRIQ® blocks the PD–L1 protein, rendering the cancer cells susceptible to attack.[242] The applicant indicated that the current standard of care drugs etoposide, carboplatin, and cisplatin impart their cytotoxic effects by interfering with the processes of DNA replication.[243] [244] Therefore, the applicant stated the mechanism of action of TECENTRIQ® is unique and distinct from other available forms of treatment for ES–SCLC.

The applicant for IMFINZI® asserted that IMFINZI® offers a novel mechanism of action for the treatment of ES–SCLC compared to the SOC chemotherapy. The applicant for IMFINZI® stated that first line SOC treatment of ES–SCLC is standard chemotherapy, including a platinum agent (typically carboplatin or cisplatin) plus etoposide.[245] The mechanism of action of platinum chemotherapy agents (including cisplatin and carboplatin) is based on the agent's ability to crosslink with the purine bases on the DNA; crosslinking interferes with DNA repair mechanisms, causes DNA damage, and subsequently induces apoptosis in cancer cells.[246] [247]

The applicant for IMFINZI® asserted that etoposide phosphate is a plant alkaloid prodrug that is converted to its active moiety, etoposide, by dephosphorylation. Further, the applicant explained etoposide causes the induction of DNA strand breaks by an interaction with DNA-topoisomerase II or the formation of free radicals, leading to cell cycle arrest, primarily at the G2 stage of the cell cycle, and cell death.[248] [249]

The applicant stated IMFINZI® is a selective, high-affinity, human IgG1κ monoclonal antibody that blocks PD–L1 binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity.[250] The applicant asserted that IMFINZI®, in combination with chemotherapy, demonstrated a statistically and clinically significant improvement in overall survival in a randomized Phase III study (CASPIAN), which is discussed later in this section.[251]

With regard to the second criterion, whether IMFINZI® and TECENTRIQ® will be assigned to the same or a different MS–DRG, the applicant for TECENTRIQ® referenced the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49445) to support that this criterion is not met in cases where the subject technology is treating a disease for which the current SOC involves non-FDA-approved therapies that are also associated with different MS–DRGs. As previously noted, the applicant stated that the current SOC treatment for ES–SCLC is a combination of etoposide, which is FDA-approved in SCLC only in combination with cisplatin, and carboplatin, which is used in preference to cisplatin for toxicity reasons, despite being off-label. The applicant for TECENTRIQ® also pointed out that irinotecan, a topoisomerase inhibitor indicated in colon and rectal cancers, is sometimes used in place of etoposide.

The applicant for TECENTRIQ® also stated that the MS–DRG payment system cannot differentiate between patients with NSCLC and ES–SCLC and noted that MS–DRGs 180 (Respiratory Neoplasms with MCC) and 181 (Respiratory Neoplasms with CC) are applicable to both diseases. The applicant for TECENTRIQ® also noted that category C34 (Malignant neoplasm of bronchus and lung) of the ICD–10–CM diagnosis coding classification system can be used to identify NSCLC and SCLC cases but does not differentiate between them. As a result, the applicant for TECENTRIQ® suggested both TECENTRIQ® and an existing technology (such as one used to treat NSCLC) may be assigned to either of these MS DRGs, even though, as previously noted, the NSCLC and SCLC patient populations are different.

The applicant for IMFINZI® asserted that extensive stage small cell lung cancer patients are identified under category C34 (Malignant neoplasm of bronchus and lung) of the ICD–10–CM coding classification system. According to the applicant for IMFINZI®, category C34 is all encompassing and does not distinguish between the lung cancer subtypes. The applicant also stated that both non-small cell lung cancer patients as well as earlier stages of small cell lung cancer (that is, limited stage) are captured under category C34, all of

phase II trial,'' *Cancer,* 1989, 63(4), pp. 638–642, doi:10.1002/1097–0142(19890215)63:4<638:aid-cncr2820630406>3.0.co;2–8.

[241] Byers, L.A., Rudin, C.M., ''Small Cell Lung Cancer: Where Do We Go from Here?,'' *Cancer,* 2014, 121(5), pp. 664–672, doi:10.1002/cncr.29098.

[242] Chen, D.S., Irving, B.A., Hodi, F.S., ''Molecular Pathways: Next-Generation Immunotherapy—Inhibiting Programmed Death-Ligand 1 and Programmed Death-1,'' *Clinical Cancer Research,* 2012, 18(24), pp. 6580–6587. doi:10.1158/1078–0432.ccr-12–1362.

[243] ETOPOPHOS (etoposide phosphate) [prescribing information]. Deerfield, IL: Baxter Healthcare, Co., 2017.

[244] Sousa, G.F.D., Wlodarczyk SR, Monteiro G., ''Carboplatin: Molecular Mechanisms of Action Associated with Chemoresistance,'' *Brazilian Journal of Pharmaceutical Sciences,* 2014, 4(50), pp. 693–701, doi:10.1590/S1984–82502014000400004.

[245] Farago, A.F., Keane, F.K., ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7, pp. 69–79.

[246] Dasari, S., Tchounwou, P.B., ''Cisplatin in cancer therapy: Molecular mechanisms of action,'' *European Journal of Pharmacology,* 2014, 740, pp. 364–378.

[247] Thirumaran R, Prendergast GC, Gilman PB, ''Cytotoxic chemotherapy in clinical treatment of cancer,'' In: Prendergast, G.C., Jaffee, E.M., editors, *Cancer Immunotherapy: Immune Suppression and Tumor Growth,* USA: Elsevier Inc, 2007, pp. 101–116, *http://dx.doi.org/10.1016/B978-012372551-6/50071-7.*

[248] Ibid.

[249] Etopophos® (etoposide phosphate) [Prescribing Information]. Princeton, NJ; Bristol-Myers Squibb, 2019.

[250] Pas-Ares, L., Jiang, H., Huang, Y., et al., A Phase III Randomized Study of First-Line Durvalumab±Tremelumimab+Platinum-based Chemotherapy (EP) vs. EP Alone in Extensive-Stage Disease Small Cell Lung Cancer (ED–SCLC):CASPIAN [Poster]. Presented at: the ASCO annual meeting, Chicago, IL June 2–6, 2017.

[251] Paz-Ares, L., Chen, Y., Reinmuth, N., et al., Overall Survival with Durvalumab Plus Platinum-Etoposide in First-Line Extensive-Stage SCLC: Results from the CASPIAN Study [presentation], Presented at: World Conference on Lung Cancer, Barcelona, Spain, September 7–10, 2019.

which have differing epidemiological considerations and treatment interventions. The applicant for IMFINZI® concluded that patients diagnosed with ES–SCLC, identified using category C34, map to MS–DRGs 180, 181, and 182 (Respiratory Neoplasms with MCC, with CC, and without CC/MCC, respectively). The applicant for IMFINZI® stated that the existing ICD–10–PCS coding system does not allow for visibility into the different MS–DRGs that ES–SCLC patients map to versus NSCLC patients, making it difficult to show that ES–SCLC patients receiving IMFINZI® would map to a unique MS–DRG from NSCLC cases, where IMFINZI® and other immuno-oncology therapies are already being used.

To further identify the patient population of interest, the applicant for IMFINZI® searched charge level data from the Premier Hospital Database to determine which MS–DRGs these cases are mapping to, beyond relying on the broad lung cancer category C34. The applicant asserted that the Premier Hospital database is a large U.S. hospital-based, all payer database that contains discharge information from geographically diverse non-governmental, community, and teaching hospitals and health systems across both rural and urban areas. The applicant for IMFINZI® stated that this database contains data from standard hospital discharge files providing access to all procedures, diagnoses, drugs, and devices received for each patient regardless of the insurance or disease state. The applicant for IMFINZI® used charge level hospital data from the Premier Hospital Database to identify cases that used category C34 as well as carboplatin or cisplatin plus etoposide, the chemotherapy doublet specifically used for ES–SCLC patients. The applicant also looked for the use of prophylactic cranial irradiation (PCI), a type of radiation therapy used for ES–SCLC patients to address the frequent occurrence of multiple brain metastases associated with SCLC. Based on this assessment of hospital charge-level data, the applicant for IMFINZI® stated that over 60 percent of ES–SCLC patients map to MS–DRGs 180 (Respiratory Neoplasms with MCC), 181 (Respiratory Neoplasms with CC), and 164 (Major Chest Procedures with CC). We agreed with the applicant that patients receiving IMFINZI® would map to the same DRGs as patients receiving standard therapy for ES–SCLC.

With regard to the third criterion, whether IMFINZI® and TECENTRIQ® will be used to treat the same or similar disease in the same or similar patient population when compared to existing therapies, the applicant for IMFINZI® stated that IMFINZI®, in combination with standard chemotherapy, represents a new treatment option for patients with extensive stage small cell lung cancer, demonstrating statistically and clinically significant improved overall survival as compared to standard chemotherapy (Hazard ratio [HR] 0.73; 95 percent CI 0.59–0.91; p=0.0047).[252] The applicant for IMFINZI® asserted that IMFINZI® in combination with chemotherapy represents a new treatment option for ES–SCLC patients. The applicant for TECENTRIQ® stated the use of TECENTRIQ® in ES–SCLC does not involve the treatment of the same or a similar type of disease and the same or similar patient population when compared to an existing technology.

We invited public comments on whether IMFINZI® or TECENTRIQ® is substantially similar to an existing technology and whether they meet the newness criterion.

In the proposed rule we stated that both IMFINZI® and TECENTRIQ® seem to be intended for similar patient populations and would involve the treatment of the same conditions: Patients with locally advanced or metastatic urothelial carcinoma and patients with SCLC. We stated that we were interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether IMFINZI® and TECENTRIQ® are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

Comment: The applicants for TECENTRIQ® and IMFINZI® each provided comments regarding whether TECENTRIQ® and IMFINZI® were substantially similar to the other, or to any existing technology.

The applicant for TECENTRIQ® (Genentech) commented that TECENTRIQ® is a humanized programmed death-ligand 1 (PD–L1) blocking antibody (which binds to PD–L1 and blocks its interactions with both PD–1 and B7.1 receptors) with multiple oncology indications, including one in combination with carboplatin and etoposide for the first-line treatment of adult patients with ES–SCLC.[253] According to the commenter, TECENTRIQ® has a total of nine indications—two in urothelial carcinoma, four in NSCLC, one in triple-negative breast cancer, one in ES–SCLC, and one in hepatocellular carcinoma.[254] The commenter stated that, in addition, TECENTRIQ® was the first cancer immunotherapy to be approved for the first line treatment of ES–SCLC, on March 18, 2019; [255] and the first drug to improve median OS in ES–SCLC which has remained at ~10 months or less since the 1980s.[256] [257] The commenter explained that over 40 Phase III trials evaluating 60+ other regimens have been attempted since 1970, none of which led to additional FDA approvals in first-line ES–SCLC.[258] Furthermore, the applicant stated that the use of TECENTRIQ® to treat ES–SCLC also amounts to a paradigm shift that was validated by the subsequent approval of IMFINZI® for an almost identical indication. According to the applicant, the combination of TECENTRIQ® with carboplatin and etoposide is also the first FDA approval for the first-line treatment of ES–SCLC since the approval of carboplatin and etoposide alone in 1999 and prior to that, the most recent approval was that of cisplatin and etoposide, in 1985.[259] The applicant asserted that, whereas TECENTRIQ® in combination with carboplatin and etoposide is associated with a statistically significant increase in overall survival and progression-free survival compared to placebo plus carboplatin and etoposide, this was not the case for the combination of KEYTRUDA (pembrolizumab), another

[252] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomized, controlled, open-label, phase 3 trial [article and supplementary appendix],'' *Lancet,* 2019.

[253] TECENTRIQ (atezolizumab) [prescribing information]. San Francisco, CA: Genentech, Inc.; 2020.

[254] TECENTRIQ (atezolizumab) [prescribing information]. San Francisco, CA: Genentech, Inc.; 2020.

[255] U.S. Department of Health and Human Services. Supplemental Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761034Orig1s019ltr.pdf.* Accessed June 11, 2020.

[256] Evans WK, Shepherd FA, Feld R, Osoba D, Dang P, Deboer G. VP–16 and cisplatin as first-line therapy for smallcell lung cancer. Journal of Clinical Oncology. 1985;3(11):1471–1477. doi:10.1200/jco.1985.3.11.1471

[257] Boni C, Cocconi G, Bisagni G, Ceci G, Peracchia G. Cisplatin and etoposide (VP–16) as a single regimen for small cell lung cancer. A phase II trial. Cancer. 1989;63(4):638–642. doi:10.1002/1097–
0142(19890215)
63:4<638::aidcncr2820630406>3.0.co;2–8.

[258] Byers LA, Rudin CM. Small cell lung cancer: Where do we go from here? *Cancer.* 2014;121(5):664–672. doi:10.1002/cncr.29098.

[259] Sabari JK, Lok BH, Laird JH, Poirier JT, Rudin CM. Unravelling the biology of SCLC: Implications for therapy. Nat Rev Clin Oncol. 2017;14(9):549–561. doi:10.1038/nrclinonc.2017.71.

well-known PD–1 blocking antibody, with either carboplatin or cisplatin, and etoposide.[260] According to the applicant, since March 2019, TECENTRIQ® in combination with carboplatin and etoposide has become the standard of care for first-line ES–SCLC, with over 60% of newly diagnosed patients receiving the regimen according to the applicant.[261]

The applicant for TECENTRIQ® stated that IMFINZI® is a human PD–L1 blocking antibody [262] (that blocks the interaction of PD–L1 with both PD–1 and CD80 receptors).[263] According to the applicant for TECENTRIQ®, IMFINZI® has indications in urothelial carcinoma, NSCLC, and, most recently, ES–SCLC.[264] The applicant explained that IMFINZI® was the second cancer immunotherapy to be approved for the first-line treatment of ES–SCLC, a little over a year after TECENTRIQ® and after the deadline for the submission of the FY 2021 new technology add-on payment application, on March 27, 2020.[265] The commenter stated that although there are slight molecular differences between TECENTRIQ® and IMFINZI®, they both fall into the same class of PD–L1 blocking antibodies. The applicant noted that if CMS believes that TECENTRIQ® and IMFINZI® are similar, then they presume CMS will consider them as a single application for purposes of new technology add-on payments in a way that was analogous to what was done for KYMRIAH and YESCARTA in FY 2019 in which both were approved for new technology add-on payments.

The applicant for IMFINZI® (AstraZeneca) commented that the addition of IMFINZI® to the standard of care—etoposide and platinum-based chemotherapy (either carboplatin or cisplatin)—offers a novel mechanism of action for the first-line treatment of ES–SCLC. Therefore, the applicant stated that IMFINZI® is not substantially similar to the standard of care because it does not have the same or similar mechanism of action. The applicant for IMFINZI® stated that it offers a new, unique treatment option for the specific patient population facing this much more aggressive form of lung cancer, small cell cancer.

The applicant for IMFINZI® asserted that IMFINZI® and TECENTRIQ® are unique molecular entities, with unique active ingredients and should be considered separately for new technology add-on payments. According to the commenter, IMFINZI® is a selective, high-affinity, human IgG1 monoclonal antibody.[266] The commenter explained that in comparison, TECENTRIQ® is a humanized monoclonal antibody.[267] [268] According to the commenter, theoretically, human antibodies, which have no non-human genetic material as humanized antibodies do, should have less immunogenicity and therefore induce less development of anti-drug antibodies (ADA).[269] Also according to the commenter, in the CASPIAN study, of those who received IMFINZI®, none of the 201 patients tested positive for treatment-emergent ADA.[270] The commenter indicated, comparatively, 18.6% of patients were reported to have treatment-emergent ADA in the TECENTRIQ® IMPower 133 study.[271] The applicant for IMFINZI® stated that the two new drugs IMFINZI® and TECENTRIQ® were evaluated in distinct and differently structured clinical trials. The commenter explained that the CASPIAN trial with IMFINZI® was studied in combination with etoposide and either carboplatin or cisplatin [272] whereas the TECENTRIQ® study omitted cisplatin as an option.[273] The applicant also noted that the inclusion of patients with asymptomatic brain metastases is another aspect of the CASPIAN trial that differentiated the expected IMFINZI® patient population according to the applicant.[274]

The applicant further stated that IMFINZI®'s unique ICD–10 procedure code which has an October 1, 2020 effective date, is distinct from that of TECENTRIQ®, to enable data to be collected specific to each technology for specific uses and patient populations, supporting a conclusion that the technologies should be considered separately for new technology add-on payments. Therefore, the manufacturer for IMFINZI® requested that CMS discretely grant new technology add-on payments for IMFINZI®, stating that current evidence does not support consideration of new technology add-on payments for IMFINZI® jointly with another applicant.

Response: We thank the applicants for their comments. After consideration of the public comments we received, although we recognize that there may be slight molecular differences, we believe IMFINZI® and TECENTRIQ® both fall into the same class of PD–L1 blocking antibodies. Also, we are not convinced that these differences result in the use of a different mechanism of action and, therefore, we believe that the two technologies' mechanisms of action are the same. Furthermore, we believe that IMFINZI® and TECENTRIQ® are substantially similar to one another because the technologies are intended to treat the same or similar disease in the same or similar patient population—patients with ES–SCLC, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action using PD–L1 blocking antibodies.

We also believe IMFINZI® and TECENTRIQ® are not substantially similar to any other existing technologies because, as both applicants asserted in their FY 2021 new technology add-on payment applications and in their comments the technologies do not use the same or similar mechanism of action to achieve a therapeutic outcome as any other

[260] Rudin CM, Awad MM, Navarro A, et al. Pembrolizumab or Placebo Plus Etoposide and Platinum as First-Line Therapy for Extensive-Stage Small-Cell Lung Cancer: Randomized, Double-Blind, Phase III KEYNOTE–604 Study [published online ahead of print, 2020 May 29]. J Clin Oncol. 2020;JCO2000793. doi:10.1200/JCO.20.00793.

[261] FlatIron EMR Data, April 2020.

[262] IMFINZI (durvalumab) [prescribing information]. Wilmington, DE: AstraZeneca Co.; 2020.

[263] Harding FA, Stickler MM, Razo J, DuBridge RB. The immunogenicity of humanized and fully human antibodies: Residual immunogenicity resides in the CDR regions. MAbs. 2010;2(3):256–265. doi:10.4161/mabs.2.3.11641.

[264] IMFINZI (durvalumab) [prescribing information]. Wilmington, DE: AstraZeneca Co.; 2020.

[265] U.S. Department of Health and Human Services. Supplemental Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/761069Orig1s018ltr.pdf*. Accessed June 21, 2020.

[266] IMFINZI® (durvalumab) [prescribing information]. Wilmington, DE. AstraZeneca, Inc.

[267] National Cancer Institute Dictionary of Cancer Terms *https://www.cancer.gov/publications/dictionaries/cancer-terms/def*. Accessed June 2020.

[268] Enrico D et al. Antidrug Antibodies Against Immune Checkpoint Blockers: Impairment of Drug Efficacy or Indication of Immune Activation? American Association for Cancer Research Journal. 2020. Volume 26 (4) 787–792. *https://clincancerres.aacrjournals.org/content/26/4/787*. Accessed June 16, 2020.

[269] Enrico D et al. Antidrug Antibodies Against Immune Checkpoint Blockers: Impairment of Drug Efficacy or Indication of Immune Activation? American Association for Cancer Research Journal. 2020. Volume 26 (4) 787–792. *https://clincancerres.aacrjournals.org/content/26/4/787*. Accessed June 16, 2020.

[270] IMFINZI® (durvalumab) [prescribing information]. Wilmington, DE. AstraZeneca, Inc.

[271] TECENTRIQ EMA Assessment report, July 25, 2019. *https://www.ema.europa.eu/en/documents/variation-report/tecentriq-h-c-004143-ii-0018-epar-assessment-report-variation_en.pdf*; accessed June 2020.

[272] Paz-Ares L, et al. Durvalumab ± tremelimumab + platinum-etoposide in first-line extensive-stage SCLC: Updated results from the phase 3 CASPIAN study. 2020 ASCO Annual meeting, abstract 9002.

[273] TECENTRIQ® (atezolizumab) [prescribing information]. South San Francisco, CA. Genentech, Inc.

[274] National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Small Cell Lung Cancer version 3.2020. Available at: *https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf*. Accessed May 2020.

existing drug or therapy assigned to the same or different MS–DRG. Based on the information described in this section, we believe IMFINZI® and TECENTRIQ® meet the newness criterion.

We also note that proposals to create, delete, or revise codes under the ICD–10–PCS structure are referred to the ICD–10 Coordination and Maintenance Committee. The decisions of this committee are independent from any decision for new technology add on payments. Therefore, we do not agree with the commenter that the fact that IMFINZI® and TECENTRIQ® have separate codes supports a conclusion that the technologies should be considered separately for new technology add-on payments.

Based on the above, we are making one determination regarding approval for new technology add-on payments that will apply to both applications, and in accordance with our policy, we use the earliest market availability date submitted as the beginning of the newness period for both IMFINZI® and TECENTRIQ®.

We believe our current policy for evaluating new technology payment applications for two technologies that are substantially similar to each other is consistent with the authority and criteria in section 1886(d)(5)(K) of the Act. We note that CMS is authorized by the Act to develop criteria for the purposes of evaluating new technology add-on payment applications. For the purposes of new technology add-on payments, when technologies are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS, for the reasons we discussed above and consistent with our evaluation of substantially similar technologies in prior rulemaking (82 FR 38120).

With respect to the newness criterion, as previously stated, IMFINZI® received FDA approval on March 27, 2020 and TECENTRIQ® received FDA approval on March 18, 2019. In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date submitted as the beginning of the newness period for both technologies. Therefore, based on our policy, with regard to both technologies, if the technologies are approved for new technology add-on payments, we believe that the beginning of the newness period would be March 18, 2019.

The applicants submitted separate cost and clinical data, and in the proposed rule, we reviewed and discussed each set of data separately. However, as stated above, for this final rule, we will make one determination regarding new technology add-on payments that will apply to both applications. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and we believe that continuing our current practice of extending new technology add-on payments without a further application from the manufacturer of the competing product, or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products to submit separate new technology add-on payment applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

If substantially similar technologies are submitted for review in different (and subsequent) years, rather than the same year, we evaluate and make a determination on the first application and apply that same determination to the second application. However, because the technologies have been submitted for review in the same year, and because we believe they are substantially similar to each other, we consider both sets of cost data and clinical data in making a determination, and we do not believe that it is possible to choose one set of data over another set of data in an objective manner.

As we discussed in the proposed rule and as stated above, each applicant submitted separate analyses regarding the cost criterion for each of their products, and both applicants maintained that their product meets the cost criterion. We summarize each analysis below.

With respect to the cost criterion, the applicant for IMFINZI® conducted the following analysis to demonstrate that IMFINZI® meets the cost criterion. To identify cases that may be eligible for the use of IMFINZI®, the applicant searched the FY 2018 MedPAR LDS file for claims reporting an ICD–10–CM code of category C34 in combination with Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.12 (Encounter for antineoplastic immunotherapy). The applicant also included any cases within MS–DRGs 180, 181, 182 with an ICD–10–CM diagnosis code from category C34 as the applicant suggested hospitals may not always capture the encounter for chemotherapy. Based on the FY 2018 MedPAR LDS file, the applicant identified a total of 24,193 cases. Of the MS–DRGs with more than 11 cases, the applicant found 23,933 cases which were mapped to 12 unique MS–DRGs. The applicant excluded MS–DRGs with case volume less than 11 total cases.

Using these 23,933 cases, the applicant for IMFINZI® then calculated the unstandardized average charges per case for each MS–DRG. The applicant determined that it did not need to remove any charges as IMFINZI® is not expected to offset historical charges already included within the MS–DRGs. The applicant asserted that ES–SCLC patients will receive their initial dose of IMFINZI® in the inpatient setting. The applicant for IMFINZI® then standardized the charges and inflated the charges by 1.11100 or 11.10 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). The applicant then added the charges for IMFINZI® by converting the costs to a charge by dividing the cost by the national average cost-to-charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179).

Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount for IMFINZI® was $53,209. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $111,093. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant for IMFINZI® maintained that the technology meets the cost criterion.

To identify cases that may be eligible for TECENTRIQ®, the applicant searched the FY 2018 MedPAR LDS file for claims reporting an ICD–10–CM code from category C34 and considered only cases where the diagnosis codes were in the primary or admitting position to differentiate ES–SCLC from limited-stage SCLC. Cases classified with one or more of 48 surgical lung procedure codes were not considered to differentiate ES–SCLC from NSCLC. This resulted in 33,404 cases, which the applicant for TECENTRIQ® indicated constitute what it defines as an ES–

SCLC case through the reconciliation of clinical presentation, applicable ICD–10–CM and ICD–10–PCS codes, and MedPAR data fields, which mapped to 264 MS–DRGs.

Using these 33,404 cases, the applicant for TECENTRIQ® then calculated the unstandardized average charges per case for each MS–DRG. The applicant determined that it did not need to remove any charges because TECENTRIQ® is administered as a combination therapy with carboplatin and etoposide to treat ES–SCLC.

The applicant for TECENTRIQ® then standardized the charges and inflated the charges by 1.11100 or 11.10 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). The applicant then added the estimated cost of an ES–SCLC TECENTRIQ® administration to the MedPAR cases. The applicant then added the charges for TECENTRIQ® by converting the costs to a charge by dividing the cost by what the applicant described as a conservative cost-to-charge ratio of 0.5.

Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount for TECENTRIQ® was $65,738. In the applicant's analysis, the final inflated average case-weighted standardized charge per case for TECENTRIQ® was $88,561. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The applicant for TECENTRIQ® also provided a sensitivity analysis using this same methodology but considered only the MS–DRGs representing 1 percent of case volume, producing a list of 10 MS–DRGs that cumulatively represent 88.31 percent of case volume, or 29,500 cases. Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case weighted threshold amount was $56,987. In the applicant's analysis, the final inflated average case-weighted standardized charge per case for TECENTRIQ® was $88,404. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The ICD–10–CM diagnosis codes and MS–DRGs in the cost analysis for IMFINZI® differ from those used in the cost analysis for TECENTRIQ®. Specifically, as noted previously, the applicant for TECENTRIQ® searched for claims with ICD–10–CM diagnosis codes from category C34 while the applicant for IMFINZI® searched for ICD–10–CM diagnosis codes from category C34 in combination with Z51.11 or Z51.12. As noted in the proposed rule, we were concerned as to why the diagnosis codes would differ between the cost analysis for IMFINZI® and for TECENTRIQ® as one analysis may lend more accuracy to the calculation depending on which is more reflective of the applicable patient population.

We invited public comment on whether IMFINZI® or TECENTRIQ® meet the cost criterion.

Comment: Genentech, the applicant for TECENTRIQ®, commented that while the cost analysis approaches taken for TECENTRIQ® and IMFINZI® are different, both independently concluded that the cost criterion was met. Regarding the contrast in selection of diagnostic codes, Genentech considered AstraZeneca's decision to include patient cases of the ICD–10–CM category C34 in combination with the ICD–10–CM codes Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.12 (Encounter for antineoplastic immunotherapy) [275] to be reasonable. However, the real-world scenario where the patient is diagnosed with ES–SCLC in the inpatient setting and then treated there due to their immediate need for treatment may not result in Z51.11 and/or Z51.12 appearing in the corresponding claim, because the inpatient stay was not solely or primarily for the administration of chemotherapy. Regarding the contrasting cost-to-charge ratios, Genentech stated that the one used by Genentech (0.5) is more conservative than that used by AstraZeneca (0.189), but both can be justified.

1. Genentech (CCR of 0.5): This was noted by CMS in the FY 2016 IPPS Final Rule, with reference to the successful application for NTAP of BLINCYTO.[276]

2. AstraZeneca (CCR of 0.189): This figure was calculated by CMS, specifically for drugs, from FY 2017 cost report data.[277]

The applicant for IMFINZI® also commented that both applicants utilized the ''C34 Malignant neoplasm of bronchus and lung'' ICD–10–CM code series (85 FR 32633).

Although the same primary diagnosis code was used, each applicant further refined the patient population using different subsequent methods. The applicant for IMFINZI® stated that the case-weighted threshold amount published in the proposed rule, using their methodology, is $65,738. Although this threshold presented in the proposed rule and the inflated case-weighted standardized charges from analyses AstraZeneca performed were calculated using different methodologies, the applicant stated that comparing them suggests that IMFINZI® would meet the cost criterion if this analysis was performed with IMFINZI® charges.

Response: We thank the applicants for their comments. We agree that both IMFINZI® and TECENTRIQ® meet the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant for IMFINZI® asserted that IMFINZI® represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to currently available treatments. The applicant for IMFINZI® also stated that it represents a substantial clinical improvement because the technology reduces mortality, decreases disease progression, and improves quality of life.

The CASPIAN clinical trial for IMFINZI® was a randomized, open-label, phase 3 trial at 209 sites across 23 countries. Eligible patients were adults with untreated ES–SCLC, with World Health Organization (WHO) performance status 0 or 1 and measurable disease as per Response Evaluation Criteria in Solid Tumors (RECIST). Patients were randomly assigned (in a 1:1:1 ratio) to durvalumab plus platinum-etoposide; durvalumab plus tremelimumab plus platinum–etoposide; or platinum-etoposide alone. All drugs were administered intravenously. Platinum-etoposide consisted of etoposide 80–100 mg/m2 on days 1–3 of each cycle with investigator's choice of either carboplatin area under the curve 5–6 mg/mL per min or cisplatin 75–80 mg/m2 (administered on day 1 of each cycle). Patients received up to four cycles of platinum-etoposide plus durvalumab 1500 mg with or without tremelimumab 75 mg every 3 weeks followed by maintenance durvalumab 1500 mg every 4 weeks in the immunotherapy groups and up to 6 cycles of platinum-etoposide every 3 weeks plus prophylactic cranial irradiation (investigator's discretion) in the platinum-etoposide group. The primary endpoint was overall survival in the intention-to-treat population. The applicant for IMFINZI® stated that the median OS was 13.0 months (95 percent CI, 11.5–14.8) for patients treated with IMFINZI® plus chemotherapy vs. 10.3 months (95 percent CI, 9.3–11.2) for

[275] 85 FR 32,633.

[276] 80 FR 49,446.

[277] 84 FR 42,179.

SOC chemotherapy. The results also showed a sustained OS benefit with 34 percent survival at 18 months following treatment with IMFINZI® plus chemotherapy vs. 25 percent following SOC chemotherapy. No data was provided on patients treated with durvalumab plus tremelimumab plus platinum-etoposide in the interim analysis submitted in the application.[278]

The applicant for IMFINZI® further stated that other key secondary endpoints demonstrated consistent and durable improvement for IMFINZI® plus chemotherapy, including a higher progression-free survival (PFS) rate at 12 months (17.5 percent vs. 4.7 percent), a 10 percent increase in confirmed objective response rate (ORR) (67.9 percent vs. 57.6 percent), and improved duration of response at 12 months (22.7 percent vs. 6.3 percent). The median progression-free Survival was 5.1 months with IMFINZI® versus 5.4 months for the control arm, which was not significantly different.

The applicant for IMFINZI® stated that in combination with etoposide and platinum-based chemotherapy, IMFINZI® provided a significant improvement in survival and notable changes in patient reported outcomes. According to the applicant, patients receiving IMFINZI® plus etoposide and platinum-based chemotherapy experienced reduced symptom burden over 12 months for pre-specified symptoms of fatigue, appetite loss, cough, dyspnea, and chest pain (based on adjusted mean change from baseline, MMRM). The applicant stated a large difference over 12 months was observed for appetite loss in favor of IMFINZI® plus etoposide and platinum-based chemotherapy compared to standard of care etoposide and platinum-based chemotherapy. The applicant further stated that patients receiving IMFINZI® plus etoposide and platinum-based chemotherapy also experienced longer time to deterioration in a broad range of patient-reported symptoms (dyspnea, appetite loss, chest pain, arm/shoulder pain, other pain, insomnia, constipation, diarrhea), functioning (physical, cognitive, role, emotional, social), and Health Related Quality of Life (HRQoL) indicators, compared to cisplatin (EP).[279] [280] [281] [282]

As stated previously, the applicant asserted that IMFINZI® represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to currently available treatments. The applicant explained that the CASPIAN study demonstrated the following endpoints: Patient population baseline characteristics, treatment exposure, overall survival (including pre-specified subgroups), progression-free survival, sites of progression, objective response rate, duration of response, and detailed safety analysis. All results provided comparison of the active IMFINZI® plus SOC chemotherapy arm to the SOC chemotherapy alone arm.[283]

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32634), we had concerns that the CASPIAN study is ongoing, and the information is preliminary. Specifically, the three arms in the study had not yet been analyzed at time of application. Additionally, while the data show a median survival benefit of about 3 months with treatment with IMFINZI®, we stated that we did not see any data that demonstrates significant improvement in median progression-free survival. Also, while we recognized that the trials are ongoing and that the analysis of the three study arms is not complete, we stated that we were interested in any updates and additional information concerning adverse events to help us better understand the safety profile of IMFINZI®.

The applicant for TECENTRIQ® asserted that TECENTRIQ® plus standard of care represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for currently available treatments. The applicant also maintained that TECENTRIQ® represents a substantial clinical improvement because the technology demonstrates statistically significant improvement in overall survival, statistically significant improvement in progression-free survival, as well as improved HRQoL (Health-related quality of life, which is an individual's or a group's perceived physical and mental health over time) [284] and reduced symptomatology.

According to the applicant, the use of TECENTRIQ® in cases of ES–SCLC was evaluated in IMpower133, a phase III (efficacy) and phase I (safety), double-blind, placebo-controlled, randomized, multicenter study designed to compare the efficacy and safety of TECENTRIQ® vs. placebo in combination with carboplatin and etoposide in patients with ES–SCLC who did not receive prior systemic therapy.[285] Over 40 percent of the population of the IMpower133 clinical trial were of Medicare age.[286]

Key inclusion criteria were as follows: Histologically or cytologically confirmed ES–SCLC as defined by the VA Lung Study Group staging system; measurable ES–SCLC according to RECIST version 1.1; ECOG PS of 0–1; no prior systemic treatment for ES–SCLC; and treated asymptomatic CNS metastases. Key exclusion criteria were as follows: History of autoimmune disease and prior treatment with CD137 agonists or immune checkpoint inhibitors.

A total of 403 patients were enrolled. Patients were stratified by gender, ECOG PS (0 or 1), and the presence of brain metastases. Baseline characteristics were comparable across both treatment arms. The following table summarizing baseline patient characteristics indicates that more than 40 percent of the patients in both treatment arms were of Medicare age.

[278] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): A randomized, controlled, open-label, phase 3 trial,'' *Lancet,* 2019, *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32222-6/fulltext.* Accessed October 7, 2019.

[279] AstraZeneca Press Release, September 9, 2019, Available at: *https://www.astrazeneca-us.com/content/az-us/media/press-releases/2019/imfinzi-is-first-immunotherapy-to-show-both-significant-survival-benefit-and-improved-durable-responses-in-extensive-stage-small-cell-lung-cancer-09092019.html.*

[280] Paz-Ares, L., Chen, Y., Reinmuth, N., et al., Overall Survival with Durvalumab Plus Platinum-Etoposide in First-Line Extensive-Stage SCLC: Results from the CASPIAN Study [presentation], Presented at: World Conference on Lung Cancer, Barcelona, Spain, September 7–10, 2019.

[281] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): A randomized, controlled, open-label, phase 3 trial,'' *Lancet.* 2019, *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32222-6/fulltext.* Accessed October 7, 2019.

[282] Paz-Ares, L., Goldman, J.W., Garassino, M.C., et al., PD–L1 expression, patterns of progression and patient-reported outcomes (PROs) with durvalumab plus platinum-etoposide in ES–SCLC: Results from CASPIAN [presentation], Presented at European Society for Medical Oncology; Barcelona, Spain, September 27-October 1, 2019.

[283] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): A randomized, controlled, open-label, phase 3 trial [article and supplementary appendix],'' *Lancet,* 2019.

[284] *https://www.cdc.gov/hrqol/index.htm.* Accessed December 27, 2019.

[285] Horn, .L, Mansfield, A.S., Szczęsna, A., et al., ''First-Line Atezolizumab plus Chemotherapy in Extensive Stage Small-Cell Lung Cancer,'' *New England Journal of Medicine,* 2018, 379(23), pp. 2220–2229, doi:10.1056/nejmoa1809064.

[286] Ibid.

Characteristic	TECENTRIQ® + Carboplatin + Etoposide (n=201)	Placebo + Carboplatin + Etoposide (n=202)
Median age (range), years	64 (28-90)	64 (26-87)
Age group, n (%)		
<65 years	111 (55.2)	106 (52.5)
≥65 years	90 (44.8)	96 (47.5)
Male, n (%)	129 (64.2)	132 (65.3)
ECOG PS, n (%)		
0	73 (36.3)	67 (33.2)
1	128 (63.7)	135 (66.8)
Tobacco use history, n (%)		
Current/previous smoker	74 (36.8)/118 (58.7)	74 (37.1)/124 (61.4)
Never smoker	9 (4.5)	3 (1.5)
Brain metastasis, yes, n (%)	17 (8.5)	18 (8.9)
Previous anticancer treatments, n (%)		
Chemotherapy or nonanthracycline	8 (4.0)	12 (5.9)*
Radiotherapy	25 (12.4)	28 (13.9)
Cancer-related surgery	33 (16.4)	25 (12.4)

*Limited-stage setting

At the time of data cutoff (April 24, 2018), the median follow-up was 13.9 months. The applicant stated that patients treated with TECENTRIQ® + carboplatin + etoposide experienced a significantly longer OS and PFS compared with patients treated with placebo + carboplatin + etoposide in the ITT population. The 1-year OS with TECENTRIQ® + carboplatin + etoposide, compared with the placebo + carboplatin + etoposide rate, was approximately 13 percent higher; the 1-year PFS was approximately 7 percent higher, as shown in the following table that summarizes Landmark Overall Survival and Progression-free Survival Rates (Data Cutoff: April 24, 2018).

	TECENTRIQ® + Carboplatin + Etoposide (n=201)	Placebo + Carboplatin + Etoposide (n=202)
12-month OS, % (95% CI)	51.7 (44.4-59.0)	38.2 (31.2-45.3)
6-month PFS, % (95% CI)	30.9 (24.3-37.5)	22.4 (16.6-28.2)
12-month PFS, % (95% CI)	12.6 (7.9-17.4)	5.4 (2.1-8.6)

The incidence of treatment-related AEs was similar in both treatment arms. The following table provides information about the safety profiles (Data Cutoff: April 24, 2018) (safety population)—IMpower133. The most common treatment-related Grade 3/4 AEs for TECENTRIQ® + carboplatin + etoposide and for placebo + carboplatin + etoposide was neutropenia (22.7 percent vs. 24.5 percent, respectively), anemia (14.1 percent vs. 12.2 percent), and decreased neutrophil count (14.1 percent vs. 16.8 percent). Treatment-related deaths occurred in three patients in the TECENTRIQ® group (due to neutropenia, pneumonia, and unspecified cause) and three patients in the placebo group (due to pneumonia, septic shock, and cardiopulmonary failure).

	TECENTRIQ® + Carboplatin + Etoposide (n=198)	Placebo + Carboplatin + Etoposide (n=196)
Treatment-related AEs, n (%)	188 (95)	181 (92)
Grades 3-4	112 (57)	110 (56)
Grade 5	3 (2)	3 (2)
SAE, n (%)	74 (37)	68 (35)
Treatment-related SAE	45 (23)	37 (19)
AEs leading to treatment withdrawal	22 (11)	6 (3)
AEs leading to withdrawal from carboplatin	5 (3)	1 (<1)
AEs leading to withdrawal from etoposide	8 (4)	2 (1)
Immune-related AEs	79 (40)	48 (25)

More patients in the TECENTRIQ® group than in the placebo group experienced immune-related AEs, with rash and hypothyroidism being the most common. The following table summarizes immune-related AEs occurring in ≥5 patients in any treatment arm (data cutoff: April 24, 2018) (safety population).

Immune-Related AEs, n (%)	TECENTRIQ® + Carboplatin + Etoposide (n=198)		Placebo + Carboplatin + Etoposide (n=196)	
	All Grades	Grades 3/4	All Grades	Grades 3/4
Rash	37 (19)	4 (2)	20 (10)	0
Hypothyroidism	25 (13)	0	1 (<1)	0
Hepatitis	14 (7)	3 (2)	9 (5)	0
Laboratory abnormalities	14 (7)	3 (2)	9 (5)	0
Infusion-related reaction	11 (6)	4 (2)	10 (5)	1 (<1)
Hyperthyroidism	11 (6)	0	5 (3)	0
Pneumonitis	4 (2)	1 (<1)	5 (3)	2 (1)

The median treatment duration of TECENTRIQ® was 4.7 months (range: 0–1), and the median number of TECENTRIQ® doses administered was 7 (range: 1–30). The median dose intensity, total cumulative dose, and median number of chemotherapy doses (four doses of carboplatin, 12 doses of etoposide) were similar in the two treatment groups.

The addition of TECENTRIQ® to carboplatin + etoposide demonstrated a statistically significant improvement in OS and PFS compared with placebo + carboplatin + etoposide for the first-line treatment of ES–SCLC. Overall, the safety profiles of TECENTRIQ® + carboplatin + etoposide and placebo + carboplatin + etoposide were comparable to the safety profiles of each individual agent; no new safety signals were identified with the combinations.

The applicant asserted that TECENTRIQ® plus standard of care therapy represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to or ineligible for currently available treatments. The applicant also asserted that TECENTRIQ® represents a significant clinical improvement over existing technologies because the technology produces a statistically significant improvement in overall survival, a statistically significant improvement in progression-free survival, as well as improved HRQoL and reduced symptomatology.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32667), we stated we were concerned that the survival benefit of the addition of TECENTRIQ® was a median duration of only 2 months over standard therapy and the improvement on the median progression-free survival was less than one month. We were also concerned that the short survival and progression-free survival may not be clinically significant. Additionally, we were concerned that the participants did not have a clinically significant improvement in their quality of life given the number of AEs in the TECENTRIQ® treatment arm combined with the number of treatments given in that arm.

We invited public comments on whether IMFINZI® or TECENTRIQ® meet the substantial clinical improvement criterion.

Comment: Multiple commenters, including the applicant for TECENTRIQ®, remarked that outcomes in ES–SCLC have been poor for decades and that the current standard therapy of platinum + etoposide chemotherapy was introduced in the 1970's. The commenters referenced multiple unsuccessful studies in the intervening decades and that TECENTRIQ® was the first advance to change that standard of care. The commenters cited the results from IMpower133, a randomized,

placebo-controlled, phase III trial, which showed that the addition of atezolizumab to standard chemotherapy significantly improved survival (Horn et al, N Engl J Med 2018).[287] The commenters also cited that adding atezolizumab to standard chemotherapy did not significantly worsen toxicity and also improved symptom control (Mansfield et al, Ann Oncol 2019).[288]

Multiple commenters, including the applicant for TECENTRIQ®, remarked that SCLC is the most aggressive type of lung cancer, accounting for 10–15% of lung cancer cases.[289] The commenters explained that the majority of these (72%) are diagnosed at the extensive stage,[290] which is associated with a 5-year survival rate of only 2.9%.[291] According to the commenters, ES–SCLC necessitates immediate treatment, and TECENTRIQ® is FDA-approved to be administered to Medicare beneficiaries on the very first day of treatment.[292] The commenters stated that ideally, this would be with the current best therapy, atezolizumab plus chemotherapy, but without the new technology add-on payment, the commenters stated that some patients will be treated with inferior therapy. The applicant stated that delaying immunotherapy is suboptimal—as a phase III study exploring immunotherapy after chemotherapy (CheckMate 451) did not improve survival (Owonikoko, ELCC 2019).

The applicant for IMFINZI® commented that the final analysis of the CASPIAN trial was presented on May 29, 2020 at the 2020 ASCO Annual Meeting.[293] According to the commenter, the final evidence supporting this indication demonstrated clinical and meaningful improvement in PFS and OS in the completed and final first experimental arm of the CASPIAN trial. According to the applicant, results from the CASPIAN trial continued to demonstrate improvement in OS vs EP, with a HR of 0.75 (95% CI 0.62–0.91; nominal p=0.0032); median OS 12.9 vs 10.5 mo, respectively. 22.2% of pts were alive at 2 y with durvalumab + cisplatin or carboplatin vs 14.4% of pts with cisplatin or carboplatin. The study concluded that the addition of durvalumab to cisplatin or carboplatin continued to demonstrate improvement in OS compared with a robust control arm, further supporting this regimen as a new standard of care for 1L ES–SCLC offering the flexibility of platinum choice.

Response: We appreciate the commenters' input and the applicants' submission of additional information to address the concerns presented in the proposed rule.

After consideration of the public comments we received, we agree that both IMFINZI® and TECENTRIQ® represent a substantial clinical improvement over existing technologies because the technologies significantly improve clinical outcomes. These two treatments are the first to show improved overall survival in the treatment of ES–SCLC, an aggressive and deadly disease, in more than 20 years. In summary, we have determined that IMFINZI® and TECENTRIQ® meet all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for IMFINZI® and TECENTRIQ® for FY 2021. As previously stated, cases involving IMFINZI® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW03336 (Introduction of durvalumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6) or XW04336 (Introduction of durvalumab antineoplastic into central vein, percutaneous approach, new technology group 6). Cases involving TECENTRIQ® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033D6 (Introduction of atezolizumab antineoplastic into peripheral vein, percutaneous approach, new technology group 6) or XW043D6 (Introduction of atezolizumab antineoplastic into central vein, percutaneous approach, new technology group 6), respectively.

Each of the applicants submitted cost information for its application. The manufacturer of IMFINZI® stated that the cost of its technology is $10,833. The applicant projected that 6,073 cases will involve the use of IMFINZI® in FY 2021. The manufacturer of TECENTRIQ® stated that the cost of its technology is $9,013.75. The applicant projected that 806 cases will involve the use of TECENTRIQ® in FY 2021. Because the technologies are substantially similar to each other, we believe using a single cost for purposes of determining the new technology add-on payment amount is appropriate for IMFINZI® and TECENTRIQ® even though each applicant has its own set of codes. We also believe using a single cost provides predictability regarding the add on payment when using IMFINZI® or TECENTRIQ® for the treatment of patients with ES–SCLC. As such, we believe that the use of a weighted average of the cost of IMFINZI® and TECENTRIQ® based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 6,879 cases (6,073 plus 806). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 86 Percent for IMFINZI® and 14 percent for TECENTRIQ®. We then multiplied the cost per case for the manufacturer specific drug by the case-weighted percentage (0.86 * $10,833 = $9,316.38 for IMFINZI® and 0.14 * $9,013.75 = $1,261.93 for TECENTRIQ®). This resulted in a case-weighted average cost of $10,578.53 for the technology. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the device or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving IMFINZI® or TECENTRIQ® is $6,875.90 for FY 2021.

i. Soliris

Alexion, Inc, submitted an application for new technology add-on payments for Soliris® (eculizumab) for FY 2021. Soliris® is approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

According to the applicant, NMOSD is a rare and severe condition that attacks the central nervous system without warning. The applicant explained that NMOSD attacks, also referred to as relapses, can cause progressive and irreversible damage to

[287] Horn L et al. *New England Journal of Medicine.* 2018;379(23):2220–2229. doi:10.1056/nejmoa1809064.

[288] Califano R et al. *Annals of Oncology.* 2018;29(suppl_10).

[289] WebMD, LLC. Types of Lung Cancer. *https://www.webmd.com/lung-cancer/Jung-cancer-types#* I. Accessed September 19, 2019.

[290] American Lung Association. Trends in Lung Cancer Morbidity and Mortality. *https://www.lung.org/assets/documents/researcb/lc-trend-report.pdf.* Published November 2014. Accessed September 19, 2019.

[291] Noone AM, Howlader N, K.rapcho M, et al. SEER Cancer Statistics Review, 1975–2015, based on November 2017 SEER data submission, posted to the SEER website, April 2018. Bethesda, MD: National Cancer Institute. 2018; *https://seer.cancer.gov/csr/1975_2015/.* Accessed Sept 19, 2019.

[292] TENCENTRIQ (atezolizumab) [prescribing information]. San Francisco, CA: Genentech, Inc.; 2019.

[293] Paz-Ares L, et al. Durvalumab ± tremelimumab + platinum-etoposide in first-line extensive-stage SCLC: Updated results from the phase 3 CASPIAN study. 2020 ASCO Annual meeting, abstract 9002.

the brain, optic nerve and spinal cord, which may lead to long-term disability, and in some instances, the damage may result in death. According to the applicant, the serious nature of an NMOSD relapse frequently requires inpatient hospitalization and treatment should be initiated as quickly as possible.

According to the applicant, in patients with AQP4 antibody-positive NMOSD, the body's own immune system can turn against itself to produce auto-antibodies against AQP4, a protein on certain cells in the eyes, brain and spinal cord that are critical for the survival of nerve cells. The applicant explained that the binding of these anti-AQP4 auto-antibodies activates the complement cascade, another part of the immune system.

According to the applicant, complement activation by anti-AQP4 auto-antibodies is one of the primary causes of NMOSD. The applicant explained that formation of membrane attack complex (MAC) is the end product of the activated complement system which is directly responsible for the damage to astrocytes leading to astrocytopathy (astrocyte death) and ensuing neurologic damage associated with NMOSD and relapses. According to the applicant, the primary goal of NMOSD treatment is to prevent these relapses, which over time lead to irreversible neurologic damage.

According to the applicant, Soliris® is a first-in-class complement inhibitor that works by selectively inhibiting the complement system, a central part of the immune system involved in inflammatory processes, pathogen elimination, activation of the adaptive immune response, and maintenance of homeostasis. The applicant explained that the complement system distinguishes between healthy host cells, cell debris, apoptotic cells, and external pathogens. The applicant further explained that the complement system triggers a modulated immune response, and functions through a combination of effector proteins, receptors, and regulators. The applicant asserted that when the complement system detects a threat, an initial protease is activated. This protease (either alone or in a complex) then cleaves its target, which in turn becomes active and starts to cleave the next target in the chain, and so on, leading to a cascade.

Per the applicant, initial activation of the complement system occurs via three different pathways, which all ultimately lead to the formation of the membrane attack complex (MAC) and release of the anaphylatoxins: (1) The classical pathway is activated by antibody-antigen complexes; (2) The alternative pathway is activated at a constant low level via ''tick-over'' (spontaneous hydrolysis) of Complement component 3 (C3), a protein of the immune system; (3) The lectin pathway is activated by carbohydrates frequently found on the surface of microbes. According to the applicant, all pathways of complement activation result in the formation of C3 convertase (''proximal complement''), and converge at the cleavage of C5 leading to the generation of C5a and C5b by the C5 convertase enzyme complexes (''Terminal complement''). The applicant explained that C3 is the most abundant complement protein in plasma, occurring at a concentration of 1.2 mg/mL and C3 cleavage products bridge the innate and the adaptive immune systems. The applicant also explained that C3a acts as an anaphylatoxin and is a mediator of inflammatory processes and C3b opsonizes the surface of recognized pathogens and facilitates phagocytosis and binds C3 convertase to form C5 convertase. The applicant also explained that C5 convertase cleaves C5 into C5a and C5b; C5a is chemotactic agent and anaphylatoxin, causing leukocyte activation, endothelial cell activation, and proinflammatory and prothrombotic effects.

According to the applicant, imbalance between complement activation and regulation leads to host tissue damage, and congenital deficiencies in the complement system can lead to an increased susceptibility to infection. The applicant explained that the complement system is also associated with the pathogenesis of non-infectious diseases such as chronic inflammation, autoimmune diseases, thrombotic microangiopathy, transplant rejection reactions, ischemic, neurodegenerative age-associated diseases, and cancer. According to the applicant, the complement system is also recognized as important in the antibody-mediated autoimmune disease AQP4 antibody-positive NMOSD. The applicant stated that Soliris® is the first and only FDA approved treatment for adult patients with NMOSD who are AQP4 antibody-positive that is proven to reduce the risk of relapse.

The incidence of NMOSD in the United States is 0.7/100,000 while the prevalence is 3.9/100,000 population.[294] The median onset of NMOSD is 39 years of age and 83 percent of cases are female.[295] [296] NMOSD was commonly misdiagnosed as multiple sclerosis (MS) in the past.[297] According to the applicant, at least two-thirds of NMOSD cases are associated with aquaporin-4 antibodies (AQP4-IgG) and complement-mediated damage to the central nervous system.

According to the applicant, Soliris® is administered via an IV infusion by a healthcare professional. The applicant explained that for adult patients with neuromyelitis optica spectrum disorder, Soliris® therapy consists of 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter. According to the applicant, Soliris® should be administered at the recommended dosage regimen time points, or within 2 days of these time points. The applicant also explained that for adult and pediatric patients with NMOSD, supplemental dosing of Soliris® is required in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion (PE/PI).

The applicant explained that Soliris® has a boxed warning for risk of serious meningococcal infections. According to the applicant, life-threatening and fatal meningococcal infections have rarely occurred in patients treated with Soliris® and can be mitigated with proper vaccination. The applicant explained that by blocking the terminal complement system, Soliris® increases the risk of meningococcal and encapsulated bacterial infection. According to the applicant, all the patients in a pivotal trial received meningococcal vaccination, and no cases of meningococcal infection were reported. The applicant also noted that Soliris® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) and under the Soliris® REMS, prescribers must enroll in the program.

With respect to the newness criterion, FDA approved Soliris® for the indication of treatment of NMOSD in adult patients who are AQP4 antibody positive on June 27, 2019. Soliris® was first approved by FDA on March 19, 2007 for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, followed by

[294] Flanagan EP, et al., ''Epidemiology of aquaporin-4 autoimmunity and neuromyelitis optica spectrum,'' *Ann Neurol,* 2016, vol. 79(5), pp. 775–783.

[295] Bukhari W, et al., ''Incidence and prevalence of NMOSD in Australia and New Zealand,'' *J Neurol Neurosurg Psychiatry,* 2017, vol. 88(8), pp. 632–638.

[296] Wingerchuk DM, et al., ''The spectrum of neuromyelitis optica,'' *Lancet Neurol,* 2007, vol. 6, pp. 805–815.

[297] Jarius S, et al., ''Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: A multicentre study of 175 patients,'' *J Neuroinflammation,* 2012, vol. 9, pp. 14.

approvals for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy, and for an efficacy supplement to add the indication of treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. The applicant has applied for new technology add-on payments for use of Soliris® only for the indication of treatment of NMOSD in adult patients who are AQP4 antibody positive. The applicant stated that FDA granted Soliris® Orphan Drug Designation for the treatment of neuromyelitis optica on June 24, 2014. Additionally, the applicant stated that Soliris® was filed as a supplemental biologics license application (sBLA; BLA125166/S–431) for the treatment of NMOSD in adult patients who are AQP4 antibody positive, which FDA assigned Priority Review status.

According to the applicant, patients with NMOSD are currently identified by ICD–10–CM diagnosis code: G36.0 Neuromyelitis optica (Devic's syndrome). The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the administration of Soliris® beginning in FY 2021 and was granted approval for the following ICD–10–PCS procedure codes effective October 1, 2020: XW033C6 (Introduction of eculizumab into peripheral vein, percutaneous approach, new technology group 6) and XW043C6 (Introduction of eculizumab into central vein, percutaneous approach, new technology group 6).

As stated previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Soliris® is the only treatment for NMOSD that works by specifically inhibiting the complement cascade as described previously. According to the applicant, Soliris® is the only FDA approved treatment for NMOSD, although several off-label products are used to treat relapse prevention in NMOSD. As mentioned previously, the applicant explained that the formation of the membrane attack complex (MAC) is the end product of the activated complement system which is directly responsible for the damage to astrocytes leading to astrocytopathy (astrocyte death) and the ensuing neurologic damage associated with NMOSD and relapses.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that cases involving the administration of Soliris® will likely be assigned to the same MS–DRGs as other therapies that are currently used but not indicated to treat NMOSD. These therapies that are used off-label include axiothiprine, rituximab, low-dose steroids (prednisone), mycophenolate mofetil, methotrexate, mitoxantrone, cyclophosphamide, tacrolimus, tocilizumab, cyclosporin A, and plasma exchange. As stated previously, the applicant asserted that Soliris® is the first approved treatment for NMOSD in adult patients who are AQP4 antibody positive.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant maintained that although Soliris® will be treating the same disease and patient population as currently available therapies, it will improve the treatment of NMOSD as there were previously no FDA labeled treatments. As stated previously, the applicant asserted that Soliris® is the first approved treatment for NMOSD in adult patients who are AQP4 antibody positive.

In summary, the applicant asserted that Soliris® meets the newness criterion because it is the only FDA approved treatment for NMOSD that works by specifically inhibiting the complement cascade. We invited public comments on whether Soliris® is substantially similar to other technologies and whether Soliris® meets the newness criterion.

Comment: One commenter asserted that the mechanism of action for Soliris® does meet the newness criterion. A second commenter observed that Soliris® was the first FDA-approved complement inhibitor indicated for the treatment of adults with AQP4 antibody-positive NMOSD, and that this is a novel therapy for NMOSD.

Response: We thank the commenters for their input concerning the application of the newness criterion to Soliris®.

Based on these comments and on information submitted by the applicant as part of its FY 2021 new technology add-on payment application for Soliris®, as discussed in the proposed rule (85 FR 32653) and previously summarized, we believe that Soliris® has a unique mechanism of action in the treatment of patients with AQP4 antibody-positive NMOSD. Therefore, we believe Soliris® is not substantially similar to existing treatment options and does meet the newness criterion. We consider the beginning of the newness period to commence when Soliris® was approved by FDA for the indication of treatment of NMOSD, on June 27, 2019.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched claims in the FY 2018 MedPAR final rule dataset reporting an ICD–10–CM diagnosis code of G36.0.

This search identified 1,151 cases primarily spanning 14 MS–DRGs. According to the applicant, cases representing patients who may be eligible for treatment with Soliris® for NMOSD would most likely map to MS–DRGs 058, 059 and 060 (Multiple Sclerosis and Cerebellar Ataxia with MCC, with CC and without CC/MCC, respectively)—the family of MS–DRGs for multiple sclerosis & cerebellar ataxia. According to the applicant, these three MS–DRGs were three of the top four MS–DRGs by volume to which cases reporting a diagnosis code G36.0 were assigned, and together these MS–DRGs accounted for about 32 percent of the 1,151 originally identified cases reporting a diagnosis code G36.0. Consequently, the applicant limited its analysis to the 376 cases that grouped to these three MS–DRGs (058, 059 and 060).

The applicant performed its cost analysis based on the 376 claims assigned to MS–DRGs 058, 059 and 060. The applicant first removed charges for other technologies. According to the applicant, Soliris® would replace other drug therapies, such as azathioprine, methotrexate, and rituximab, among others. Because it is generally not possible to differentiate between different drugs on inpatient claims, the applicant removed all charges in the drug cost center. The applicant also removed all charges from the blood cost center, because Soliris® will replace plasma exchange procedures. Lastly, the applicant removed an additional $12,000 of cost for the plasma exchange procedural costs, based on an internal analysis of the average cost of plasma exchange. To convert these costs to charges, the applicant used the ''other services'' national average cost-to-charge ratio (0.346). According to the applicant, this was likely an overestimate of the charges that would be replaced by using Soliris®.

After removing charges for the prior technology to be replaced, the applicant standardized the charges. The applicant

then used the 2-year inflation factor of 11.1 percent, as published in the FY 2020 IPPS final rule (84 FR 42629), to inflate the charges from FY 2018 to FY 2020. To determine the charges for Soliris®, the applicant assumed hospitals would use the inverse of the national average cost to charge ratio for pharmacy costs (0.189) from the FY 2020 IPPS/LTCH PPS final rule to mark-up charges.

Based on the aforementioned analysis, the applicant computed a final inflated average case-weighted standardized charge per case of $72,940, as compared to a calculated threshold value of $44,420. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We note that, in the proposed rule, we inadvertently omitted the charges for Soliris® in the applicant's cost analysis. After accounting for these charges, the applicant computed a final inflated average case-weighted standardized charge per case of $172,867, which exceeds the calculated threshold value of $44,420. However, as previously noted, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount even without the addition of charges for Soliris®. We invited public comments on whether Soliris® meets the cost criterion.

We did not receive any public comments on whether Soliris® meets the cost criterion. Based on the information submitted by the applicant as part of its FY 2021 new technology add-on payment application for Soliris®, as discussed in the proposed rule (85 FR 32652 through 32655) and previously summarized, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, Soliris® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Soliris® represents a substantial clinical improvement over existing technologies because it significantly improves clinical outcomes relative to services or technologies previously available, as demonstrated by the applicant's clinical data and patient outcomes, such as the prevention of relapses in patients with NMOSD.

The applicant provided a randomized, controlled trial in support of its claims of reduction of first-adjudicated on-trial relapse with Soliris® (PREVENT).[298] The PREVENT study enrolled 143 adults who were randomly assigned in a 2:1 ratio to receive intravenous eculizumab (at a dose of 900 mg weekly for the first four doses starting on day 1, followed by 1200 mg every 2 weeks starting at week 4) or a matched placebo. The continued use of stable-dose immunosuppressive therapy was permitted. The primary endpoint studied was the first adjudicated relapse. Secondary outcomes included the adjudicated annualized relapse rate, quality-of-life measures, and the score on the Expanded Disability Status Scale (EDSS), which ranges from 0 (no disability) to 10 (death). Adjudicated relapses occurred in 3 of 96 patients (3 percent) in the Soliris® group and 20 of 47 (43 percent) in the placebo group (hazard ratio, 0.06; 95 percent confidence interval [CI], 0.02 to 0.20; P<0.001). The adjudicated annualized relapse rate was 0.02 in the eculizumab group and 0.35 in the placebo group (rate ratio, 0.04; 95 percent CI, 0.01 to 0.15; P<0.001). The applicant also explained that 97.9 percent of patients on Soliris® remained NMOSD relapse free at 48 weeks, 96.4 percent at 96 weeks and 96.4 percent at 144 weeks. There was no significant between-group difference in measures of disability progression. The mean change in the EDSS score was −0.18 in the eculizumab group and 0.12 in the placebo group (least-squares mean difference, −0.29; 95% CI, −0.59 to 0.01).

The applicant also submitted a poster presentation of post hoc efficacy analyses in pre-specified subgroups from the PREVENT study.[299] Pre-specified subgroup summaries for time to first adjudicated relapse were based on immunosuppressive therapies (IST) use (five subgroups for concomitant IST use; two subgroups according to whether or not rituximab was previously used), geographic region, age, sex, race and randomization stratum. Time to first adjudicated relapse was increased with eculizumab compared with placebo in all subgroups analyzed. Significant treatment effects were observed in all subgroups for IST use, region, age, sex and race, except for the smallest subgroups in which the differences were similar to the others but did not reach nominal significance owing to small sizes (patients using other ISTs, n = 7; Black/African American patients, n = 17, among whom none of the nine patients receiving eculizumab experienced a relapse), and in patients from the Americas owing to the performance of the placebo arm. In patients who had received rituximab more than 3 months before the study, the adjudicated relapse risk reduction was 90.7 percent with eculizumab compared with placebo (p = 0.0055). The proportion of patients who were relapse-free at week 48 was consistently higher with eculizumab than with placebo in all pre-specified IST subgroups.

As stated previously, the applicant asserted that Soliris® represents a substantial clinical improvement over existing technologies because it reduces relapses in patients with NMOSD. The applicant explained that the PREVENT study demonstrated several endpoints. The applicant explained that Soliris® reduced first adjudicated on-trial relapse with eculizumab in comparison to placebo with a 94 percent relative risk reduction (Hazard Ratio, 0.006; 95% CI, 0.02–0.20). The applicant also explained that 97.9 percent of Soliris® patients were relapse free at 48 weeks, compared to 63.2 percent for the placebo group. The applicant further noted that in a subgroup of patients utilizing monotherapy (patients on eculizumab or placebo only, without concomitant immunosuppressant agents), 100 percent of Soliris® patients were relapse free at 48 weeks compared to 60.6 percent for placebo. The applicant also explained that in the PREVENT subgroup analysis presented as a poster, the treatment effect was observed regardless of whether it was used as a monotherapy or with concomitant ISTs (corticosteroids alone, azathioprine, mycophenolate mofetil); previous IST use (including rituximab); geographical region; age; sex; and race.

The applicant also explained that the Soliris® U.S. Prescribing Information contains the following information on resource utilization in the applicant's phase III trials (corticosteroid use, plasma exchange treatment, and hospitalizations): Compared to placebo-treated patients, the PREVENT study showed that Soliris®-treated patients had reduced annualized rates of (1) hospitalizations (0.04 for Soliris® versus 0.31 for placebo), (2) of corticosteroid administration to treat acute relapses

[298] Pittock, S.J., Berthele, A., Fujihara, K., Kim, H.J., Levy, M., Palace, J., Nakashima, I., Terzi, M., Totolyan, N., Viswanathan, S., Wang, K.C., Pace, A., Futita, K.P., Armstrong, R., Wingerchuk, D.M., ''Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder.'' *N Engl J Med.,* 2019, vol 381(7), pp., 614–625.

[299] Pittock, S.J., Berthele, A., Fujihara, K., Kim, H.J., Levy, M., Palace, J., Nakashima, I., Terzi, M., Totolyan, N., Viswanathan, S., Wang, K.C., Pace, A., Futita, K.P., Yountz, M., Armstrong, R., Wingerchuk, D.M., ''Subgroup analyses from the phase 3 PREVENT study in patients with aquaporin-4 antibody-positive neuromyelitis optica spectrum disorder,'' September 11–13, 2019, Poster presentation at ECTRIMS, Stockholm, Sweden.

(0.07 for Soliris® versus 0.42 for placebo), and (3) of plasma exchange treatments (0.02 for Soliris® versus 0.19 for placebo). The applicant explained that annualized rates were calculated by dividing the total number of on-trial relapses requiring acute treatment during the study period for all patients by the number of patient-years in the study period.

After reviewing the information submitted by the applicant as part of its FY 2021 new technology add-on payment application for Soliris, we stated in the proposed rule that we are concerned that the applicant provided only one study in support of its assertions of substantial clinical improvement, which is the PREVENT trial, with additional supporting documents all based on the same trial. We noted that the study compared Soliris to placebo but that there was no comparison of Soliris to currently available treatments to gauge real world efficacy, nor was there information about how these current treatments work and why they are ineffective. Furthermore, in the PREVENT trial, the applicant did not provide the dosage amounts for the patients on continuing medication in addition to placebo or Soliris. We stated that it is not clear to us if the patients receiving Soliris had higher dosages of continuing medications than those in the placebo group. We stated that we would be interested in more information about the dosage amounts in the treatment and control groups in the PREVENT trial. We invited public comment on whether Soliris® technology meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments in response to CMS's concerns in the proposed rule regarding whether Soliris® meets the substantial clinical improvement criterion.

With respect to the concern that the applicant provided only one study in support of its assertions of substantial clinical improvement, the PREVENT trial, the applicant responded that although evidence from two or more well-controlled studies is a common benchmark for demonstrating efficacy, regulatory agencies (including FDA) have acknowledged that a single adequate and well-controlled study can, in some circumstances, constitute sufficient basis for a demonstration of clinical efficacy. According to the applicant, reliance on single studies is typically limited to situations in which the trial has demonstrated a clinically meaningful effect on mortality or irreversible morbidity, and confirmation of the result with a second trial would be practically or ethically difficult to carry out. The applicant noted in this context that clinical trials for NMOSD in particular present challenges due to the rarity of the disease, ethical concerns regarding placebo-controlled designs, and a lack of validated outcome measures or biomarkers.

According to the applicant, the PREVENT study was an adequately designed and well-controlled trial based on general FDA guidance on rare disease clinical trials and on specific recommendations made by the Center for Drug Evaluation and Research. The applicant reiterated that the PREVENT study was a large, multicenter study, involved a double-blind randomized design, and enrolled patients who demonstrated a large unmet medical need (≥2 relapses in previous 12 months, or ≥3 relapses in previous 24 months with a least one relapse in the previous 12 months). The applicant also pointed out that many of these patients were on corticosteroids and immunosuppressive therapies (ISTs), which are used off-label in patients with NMOSD. Finally, the applicant repeated several of the core findings from the PREVENT trial, with regard to the comparative effectiveness of Soliris.

With respect to the concern that the PREVENT trial compared Soliris to placebo, but that there was no comparison of Soliris to currently available treatments to gauge real world efficacy, the applicant responded that at the start of the PREVENT trial, there were no other FDA-approved therapies for managing NMOSD. The applicant further asserted that even today, the other off-label immunosuppressant therapies (ISTs) used in the treatment of NMOSD (including corticosteroids, mycophenolate mofetil, azathioprine, tacrolimus, and rituximab) are employed primarily based on empiric evidence, but there is no uniform consensus on appropriate standard of care. Given this, in order to evaluate the efficacy of Soliris in NMOSD, a randomized, placebo-controlled trial was necessary, according to the applicant.

The applicant also noted that the PREVENT trial included comparisons involving several of the available IST treatments, when used with Soliris, to use of the same IST treatments with placebo. The PREVENT trial included an eculizumab arm and a placebo arm, and patients in both arms could continue to receive ISTs (including corticosteroids, azathioprine, and/or mycophenolate mofetil) at stable dosages throughout the study. According to the applicant, the PREVENT trial demonstrated statistically persuasive findings showing the effectiveness of Soliris in preventing NMOSD relapses, including among the subset of study patients who also received maintenance treatment with ISTs.

With respect to the concern that the applicant did not provide information about how the alternative IST treatments for NMOSD work, and why these are ineffective, the applicant asserted that it cannot explain how these current, off-label treatments work, but the available data, which are primarily from case reports and small prospective or retrospective studies, suggest that these alternatives are not effective.

According to the applicant, current treatment goals for NMOSD rely on long-term stabilization of disease course by preventing relapses and relapse-associated symptoms. The available efficacy and safety data for the use of non-FDA-approved therapies in patients with NMOSD is primarily from case reports and small prospective or retrospective studies. In addition, despite increasingly common use of rituximab off-label as a preferred therapy in NMOSD, experience in patients with NMOSD is mostly derived from retrospective analyses. According to the applicant, approximately one-third of patients enrolled in PREVENT had previously received rituximab, but not within 3 months before enrolling in PREVENT.

The applicant then asserted that available data show that current IST treatments are not effective in the long-term control of NMOSD. The applicant noted data from a study showing that the five-year prognosis of patients with AQP4-IgG seropositive NMOSD is:

- 55% relapse within one year of onset;
- 22% required canes, crutches, or braces to walk (95% CI 15%–29%);
- 8% restricted to bed, chair, or wheelchair (95% CI 3%–13%);
- 41% legally blind in one or both eyes (95% CI 33%–50%); and
- 9% legally blind in both eyes (95% CI 4%–14%) [300]

The applicant concluded that in the PREVENT trial, the hazard ratio based on a stratified Cox proportional hazards model for relapse was 0.06 (95% CI, 0.02 to 0.20) indicating that Soliris-treated patients experienced a 94% relative relapse risk reduction ($p < 0.0001$) compared to patients on placebo. The time to the first adjudicated on-trial relapse was significantly longer in eculizumab-

[300] Jiao Y, et al. Neurology. 2013;81(14):1197–1204.

treated patients compared to placebo-treated patients (p <0.0001).

With regard to the concern that it was not clear if the patients in the PREVENT study who received Soliris had higher dosages of continuing IST medications than those in the placebo group, the applicant provided additional information on the dosage of those medications. The applicant acknowledged that the inclusion of patients receiving concomitant ISTs in PREVENT raised the possibility that the treatment effect ascribed to Soliris might have resulted from one of the other background therapies instead. However, the applicant asserted that several approaches were taken in PREVENT to mitigate the potentially confounding influence of concomitant ISTs. In particular, background IST dosages were not permitted to change during the trial, to ensure that increased IST dosages did not confound efficacy evaluations. Also, the total daily corticosteroid dose should not have exceeded 20 mg/day of prednisone or equivalent, to ensure that no significant imbalance between groups in regards to corticosteroid use could exist.

The applicant also provided additional data showing that the average doses of concomitant ISTs (Azathioprine; Corticosteroids; Mycophenolate Mofetil) in patients randomized to the eculizumab and placebo groups in PREVENT were similar, thereby arguing against any imbalance between treatment groups that may have influenced the efficacy results.

In addition, several other commenters wrote letters of support for the Soliris® new technology add-on payment application, in which they asserted that Soliris® had been shown effective in the PREVENT trial, and therefore that Soliris® meets the substantial clinical improvement criterion. A few of the commenters cited their own clinical experience in working with NMOSD patients, and either described the potential value of Soliris® based on their own experience, or based on the unique mechanism of action of Soliris®.

Response: We appreciate the commenters' input, including the additional information and analysis provided by the applicant in response to our concerns regarding substantial clinical improvement. After reviewing the information submitted by the applicant addressing our concerns raised in the proposed rule, we agree with the applicant that Soliris® represents a substantial clinical improvement over existing technologies because, based on the information provided by the applicant, the technology offers a treatment option for preventing relapses and improving long-term outcomes in the treatment of NMOSD, for which it is the first and only FDA approved treatment.

After consideration of the public comments we received, we have determined that Soliris® meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for Soliris® for FY 2021. Cases involving the use of Soliris® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033C6 and XW043C6.

In its application, the applicant stated that Soliris® is available in a 30ml package with a strength of 10mg/1ml. According to the applicant, the WAC per package of Soliris® is $6,523. The applicant stated that the typical patient will receive a 900mg dose each week the patient is in the hospital, which is equivalent to three packages for a cost of $19,569 per week. Based on the cases in the applicant's sample, the applicant calculated that the average cost per hospital visit per patient for Soliris® is $28,416.69, which is approximately 1.45 doses per hospital stay. However, according to FDA labeling, all packages of Soliris® are single-dose. Therefore, we have determined that cases involving Soliris® would incur an average cost of $32,615, which is the equivalent of 5 packages (900mg per dose × 1.45 doses per hospital stay = 1,305mg per hospital stay/300mg per package = 4.35 vials). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the costs of the new medical service or technology, or 65 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, the maximum new technology add-on payment for a case involving the use of Soliris® is $21,199.75 for FY 2021.

k. The SpineJack® System

Stryker, Inc., submitted an application for new technology add-on payments for the SpineJack® Expansion Kit (hereinafter referred to as the SpineJack® system) for FY 2021. The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement.

The applicant explained that the SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. According to the applicant, once in place, the intravertebral implants are expanded to mechanically restore VB height and maintain the restoration. The applicant explained that the implants remain within the VB and, together with the delivered bone cement, stabilize the restoration, provide pain relief and improve patient mobility. According to the applicant, the SpineJack® system further reduces the risk of future adjacent level fractures (ALFs).[301]

The applicant explained that the SpineJack® system is available in three sizes (4.2, 5.0 and 5.8 mm), and implant size selection is based upon the internal cortical diameter of the pedicle. According to the SpineJack® system Instructions for Use, the use of two implants is recommended to treat a fractured VB. According to the applicant, multiple VBs can also be treated in the same operative procedure as required.

The applicant explained that using a bilateral transpedicular approach, the SpineJack® implants are inserted into the fractured VB. The applicant stated that the implants are then progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other in situ to mechanically restore VB height. The applicant explained that the mechanical working system of the implant allows for a progressive and controlled reduction of the vertebral fracture.[302] The applicant stated that when expanded, each SpineJack® system implant exerts a lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack, and that the longitudinal compression on the implant causes it to open in a craniocaudal direction. The applicant explained that the implant is locked into the desired expanded position as determined and controlled by the treating physician.[303]

The applicant further explained that once the desired expansion has been

[301] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study),'' The Spine Journal, November 2019, vol 19(11), pp. 1782–1795.

[302] Vanni D., et al., ''Third-generation percutaneous vertebral augmentation systems,'' J. Spine Surg., 2016, vol. 2(1), pp. 13–20.

[303] Noriega D. et al., ''Clinical Performance and Safety of 108 SpineJack Implantations: 1-Year Results of a Prospective Multicentre Single-Arm Registry Study,'' BioMed Res. Int., 2015, vol. 173872.

obtained, polymethylmethacrylate (PMMA) bone cement is injected at low pressure into and around the implant to stabilize the restored vertebra, which leads the implant to become encapsulated with the delivered bone cement. According to the applicant, restoration of the anatomy and stabilization of the fracture results in pain relief as well as improved mobility for the patient.[304]

According to the applicant, osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals. The applicant explained that in 2010, approximately 54 million Americans aged 50 years or older had osteoporosis or low bone mass,[305] which resulted in more than 2 million osteoporotic fragility fractures in that year alone.[306] The applicant stated it has been estimated that more than 700,000 VCFs occur each year in the United States (U.S.),[307] and of these VCFs, about 70,000 result in hospital admissions with an average length of stay of 8 days per patient.[308] Furthermore, the applicant noted that in the first year after a painful vertebral fracture, patients have been found to require primary care services at a rate 14 times greater than the general population.[309] The applicant explained that medical costs attributed to VCFs in the U.S. exceeded $1 billion in 2005 and are predicted to surpass $1.6 billion by 2025.[310]

The applicant explained that osteoporotic VCFs occur when the vertebral body (VB) of the spine collapses and can result in chronic disabling pain, excessive kyphosis, loss of functional capability, decreased physical activity and reduced quality of life. The applicant stated that as the spinal deformity progresses, it reduces the volume of the thoracic and abdominal cavities, which may lead to crowding of internal organs. The applicant noted that the crowding of internal organs may cause impaired pulmonary function, abdominal protuberance, early satiety and weight loss. The applicant indicated that other complications may include bloating, distention, constipation, bowel obstruction, and respiratory disturbances such as pneumonia, atelectasis, reduced forced vital capacity and reduced forced expiratory volume in 1 second.

The applicant stated that if VB collapse is >50 percent of the initial height, segmental instability will ensue. As a result, the applicant explained that adjacent levels of the VB must support the additional load and this increased strain on the adjacent levels may lead to additional VCFs. Furthermore, the applicant summarized that VCFs also lead to significant increases in morbidity and mortality risk among elderly patients, as evidenced by a 2015 study by Edidin et al., in which researchers investigated the morbidity and mortality of patients with a newly diagnosed VCF (n=1,038,956) between 2005 to 2009 in the U.S. Medicare population. For the osteoporotic VCF subgroup, the adjusted 4-year mortality was 70 percent higher in the conservatively managed group than in the balloon kyphoplasty procedures (BKP)-treated group, and 17 percent lower in the BKP group than in the vertebroplasty (VP) group. According to the applicant, when evaluating treatment options for osteoporotic VCFs, one of the main goals of treatment is to restore the load-bearing bone fracture to its normal height and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra and in this way, the intraspinal disc pressure is restored and the risk of adjacent level fractures (ALFs) is reduced.

The applicant explained that treatment of osteoporotic VCFs in older adults most often begins with conservative care, which includes bed rest, back bracing, physical therapy and/or analgesic medications for pain control. According to the applicant, for those patients that do not respond to conservative treatment and continue to have inadequate pain relief or pain that substantially impacts quality of life, vertebral augmentation (VA) procedures may be indicated. The applicant explained that VP and BKP are two minimally invasive percutaneous VA procedures that are most often used in the treatment of osteoporotic VCFs and another VA treatment option includes the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

According to the applicant, among the treatment options available, BKP is the most commonly performed procedure and the current gold standard of care for VA treatment. The applicant stated that it is estimated that approximately 73 percent of all vertebral augmentation procedures performed in the United States between 2005 and 2010 were BKP.[311] According to the applicant, the utilization of the Kiva® system is relatively low in the U.S. and volume information was not available in current market research data.[312]

The applicant stated that VA treatment with VP may alleviate pain, but it cannot restore VB height or correct spinal deformity. The applicant stated that BKP attempts to restore VB height, but the temporary correction obtained cannot be sustained over the long-term. The applicant stated that the Kiva® implant attempts to mechanically restore VB height, but it has not demonstrated superiority to BKP for this clinical outcome.[313]

With respect to the newness criterion, the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, based on a determination of substantial equivalence to a legally marketed predicate device. We note, except for this paragraph summarizing FDA clearance documentation and market availability, we refer to the SpineJack® Expansion Kit in this final rule as the SpineJack® system. The applicant explained that although the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, due to the time required to prepare for supply and distribution channels, it was not available on the U.S. market until October 11, 2018. As we discussed previously, the SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic VCFs and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cements. In the FY 2021 IPPS/LTCH PPS proposed rule, we noted that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the implantation of the SpineJack® Expansion Kit beginning in FY 2021. The applicant was granted approval for

[304] Ibid.

[305] National Osteoporosis Foundation. (2019). What is osteoporosis and what causes it? Available from: *https://www.nof.org/patients/what-isosteoporosis/*.

[306] King A and Fiorentino D. ''Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures.'' Health Affairs (Millwood), 2011, vol. 30(12), pp. 2362–2370.

[307] Riggs B and Melton L. ''The worldwide problem of osteoporosis: Insights afforded by epidemiology.'' Bone, 1995, vol. 17(Suppl 5), pp. 505–511.

[308] Siemionow K and Lieberman I. ''Vertebral augmentation in osteoporotic and osteolytic fractures: Current Opinion in Supportive and Palliative Care.'' 2009, vol. 3(3), pp. 219–225.

[309] Wong C and McGirt M. ''Vertebral compression fractures: A review of current management and multimodal therapy.'' Journal of Multidisciplinary Healthcare, 2013, vol 6, pp. 205–214.

[310] Burge R et al. ''Incidence and economic burden of osteoporosis-related fractures in the United States: 2005–2025.'' Journal of Bone and Mineral Research. 2007, vol 22(3), pp. 465–475.

[311] 0 Goz V et al. ''Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010.'' The Spine Journal. 2015, vol. 15(5), pp. 959–965.

[312] Lin M. ''Minimally invasive vertebral compression fracture treatments. Medtech 360, Market Insights, Millennium Research Group. 2019.

[313] Ibid.

the following procedure codes: XNU0356 (Supplement lumbar vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6) and XNU4356 (Supplement thoracic vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, there are several factors that highlight the different mechanism of action in treating osteoporotic VCFs with the SpineJack® system compared to other BKP implants to reduce the incidence of ALFs and improve midline VB height restoration. According to the applicant, these differences include implant construction, mechanism of action, bilateral implant load support and >500 Newtons (N) of lift pressure.

The applicant described the SpineJack® system as including two cylindrical implants constructed from Titanium-6-Aluminum-4-Vanadium (Ti6Al4V) with availability in three sizes 4.2 mm (12.5 mm expanded), 5.0 mm (17 mm expanded) and 5.8 mm (20 mm expanded).

According to the applicant, the SpineJack® system implant exerts lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack. The applicant explained that following the insertion of the implant into the vertebral body (VB), it is progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other and the longitudinal compression on the implant causes it to open in a craniocaudal direction. According to the applicant, the force generated by the bilateral the SpineJack® system implants varies according to implant size, ranging from 500–1,000 Newtons for fracture reduction and superior endplate lift. In addition, the applicant explained that the SpineJack® system implant provides symmetric, broad load support under the fractured endplate and spinal column which differentiates the mechanism of action from BKP.[314]

The applicant stated that the SpineJack® system implant is uniquely constructed from a titanium alloy, which the applicant claims allows for plastic deformation when it encounters the hard cortical bone of the endplate yet still provides the lift force required to restore midline VB height in the fractured vertebra. The applicant stated that the SpineJack® system notably contains a self-locking security mechanism that restricts further expansion of the device when extreme load forces are concentrated on the implant. As a result, the applicant asserted that this feature significantly reduces the risk of vertebral endplate breakage while it further allows functional recovery of the injured disc.[315]

According to the applicant, the expansion of the SpineJack® system implants creates a preferential direction of flow for the bone cement; PMMA bone cement is deployed from the center of the implant into the VB. The applicant stated that when two implants are symmetrically positioned in the VB, this allows for a more homogenous spread of PMMA bone cement. The applicant asserted that the interdigitation of bone cement creates a broad supporting ring under the endplate, which is essential to confer stability to the VB.

The applicant explained that the SpineJack® system implants provide symmetric, broad load support for osteoporotic vertebral collapse, which is based upon precise placement of bilateral ''struts'' that are encased in PMMA bone cement, whereas BKP and vertebroplasty (VP) do not provide structural support via an implanted device. The applicant explained that the inflatable balloon tamps utilized in BKP are not made from titanium and are not a permanent implant. According to the applicant, the balloon tamps are constructed from thermoplastic polyurethane, which have limited load bearing capacity. The applicant noted that although the balloon tamps are expanded within the VB to create a cavity for bone cement, they do not remain in place and are removed before the procedure is completed. The applicant explained that partial lift to the VB is obtained during inflation, resulting in kyphotic deformity correction and partial gains in anterior VB height restoration, but inflatable balloon tamps are deflated prior to removal so some of the VB height restoration obtained is lost upon removal of the bone tamps. According to the applicant, BKP utilizes the placement of PMMA bone cement to stabilize the fracture and does not include an implant that remains within the VB to maintain fracture reduction and midline VB height restoration.

According to the applicant, the Kiva® system is constructed of a nitinol coil and PEEK–OPTIMA sheath, with sizes including a 4-loop implant (12 mm expanded) and a 5-loop implant (15 mm expanded), and unlike the SpineJack® system, is not made of titanium and does not include a locking scissor jack design. The applicant stated that the specific mechanism of action for the Kiva® system is different from the SpineJack® system. The applicant explained that during the procedure that involves implanting the Kiva® system, nitinol coils are inserted into the VB to form a cylindrical columnar cavity. The applicant stated that the PEEK–OPTIMA is then placed over the nitinol coil. The applicant explained that the nitinol coil is removed from the VB and the PEEK material is filled with PMMA bone cement. The applicant stated that the deployment of 5 coils equates to a maximum of height of 15 mm. The applicant stated that the lifting direction of the Kiva® system is caudate and unidirectional. According to the applicant, in the KAST (Kiva Safety and Effectiveness Trial) pivotal study, it was reported that osteoporotic VCF patients treated with the Kiva® system had an average of 2.6 coils deployed.[316] Additionally, in a biomechanical comparison conducted for the Kiva® system and BKP using a loading cycle of 200–500 Newtons in osteoporotic human cadaver spine segments filled with bone cement, there were no statistically significant differences observed between the two procedures for VB height restoration, stiffness at high or low loads, or displacement under compression.[317]

The applicant summarized the differences and similarities of the SpineJack® system, BKP, and PEEK coiled implant as follows: (1) With respect to construction, the SpineJack® system is made of Titanium-6-Aluminum-4-Vanadium compared to

[314] Jacobson R et al. ''Re-expansion of osteoporotic compression fractures using bilateral SpineJack implants: Early clinical experience and biomechanical considerations.'' Cureus. 2019, vol 11(4), e4572.

[315] Vanni D et al. ''Third-generation percutaneous vertebral augmentation systems.'' Journal of Spine Surgery. 2016, vol 2(1), pp. 13–20.

[316] Tutton S et al. KAST Study: The Kiva system as a vertebral augmentation treatment—a safety and effectiveness trial: A randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. Spine. 2015; 40(12):865–875.

[317] Wilson D et al. An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty. Clinical Biomechanics. 2012; 27(4):346–353.

thermoplastic polyurethanes for BKP and nitinol and PEEK for the PEEK coiled implant; (2) with respect to mechanism of action, the SpineJack® system uses a locking scissor jack encapsulated in PMMA bone cement compared to hydrodynamic cavity creation and PMMA cavity filler for BKP and coil cavity creation and PEEK implant filled with PMMA bone cement for the PEEK coiled implant; (3) with respect to plastic deformation, the SpineJack® system and BKP allow for plastic deformation while the PEEK coiled implant does not; (4) with respect to craniocaudal expansion, the SpineJack® system allows for craniocaudal expansion, whereas BKP and the PEEK coiled implant do not; (5) with respect to bilateral load support, the SpineJack® system provides bilateral load support whereas BKP and the PEEK coiled implant do not; and (6) with respect to lift pressure of >500 N, the SpineJack® system provides lift pressure of >500 N whereas BKP and the PEEK coiled implant do not. The applicant summarized that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than BKP, which is the gold standard of treatment for osteoporotic VCFs, and that the construction and mechanism of action of the SpineJack® system is further differentiated when compared with the PEEK coiled implant.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant did not specify whether it believed cases involving the SpineJack® system would be assigned to the same MS–DRG as existing technology. However, we note that the MS–DRGs the applicant included in its cost analysis were the same MS–DRGs to which cases involving BKP procedures are typically assigned.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant did not specifically address whether the technology meets this criterion. However, the applicant generally summarized the disease state that the technology treats as osteoporotic VCFs, and described other treatment options for osteoporotic VCFs as including VP, BKP and the PEEK coiled implant.

In summary, the applicant asserted that the SpineJack® system is not substantially similar to any existing technology because it utilizes a different mechanism of action, when compared to existing technologies, to achieve a therapeutic outcome.

We invited public comments on whether the SpineJack® system is substantially similar to other currently available technologies and whether the SpineJack® system meets the newness criterion.

Comment: Several commenters expressed their specific and general support for approval of the SpineJack® system for new technology add-on payment. Many of these commenters shared their academic knowledge of and first-hand clinical experience with vertebral augmentation procedures, including claims of familiarity and expertise with the use of the Kiva® system, BKP and the SpineJack® system. According to many of these commenters, the SpineJack® system provides a significant benefit beyond that which is achieved by other vertebral augmentation technology. Many commenters also indicated that the price compared to the reimbursement rate has been an impediment to use of the SpineJack® system in some cases. Finally, several of these commenters expressed their belief that the SpineJack® system may reduce costs to hospitals and the U.S. health system overall by preventing the onset of additional adjacent fractures in patients.

Response: We thank the commenters for the analysis and feedback provided.

Comment: The applicant submitted a comment restating information that was previously provided in their application for new technology add-on payment and described in the proposed rule and previously in this final rule. According to the applicant, the SpineJack® system meets the newness criterion, because it received FDA 510(k) clearance on August 30, 2018, and was commercially available in the United States on October 11, 2018. The applicant also explained that based on the information submitted in the application for new technology add-on payment, specifically regarding implant construction, mechanism of action, bilateral implant load support and lift pressure, the SpineJack® system has a unique mechanism of action to achieve a therapeutic outcome, compared to other VCF treatments.

In response to CMS' concern that the applicant did not specify whether it believed cases involving the SpineJack® system would be assigned to the same MS–DRGs as existing technology, the applicant provided additional clarification, and acknowledged that the SpineJack® system would be assigned to the same MS–DRGs as existing technology for vertebral augmentation.

In response to CMS' concern that the applicant did not specifically address whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the SpineJack® system is used in the reduction of osteoporotic VCFs, and does target the same or similar type of disease and the same or similar patient population as targeted by VP, BKP and other mechanical vertebral augmentation systems.

Two commenters asserted that the applicant's description of the mechanism of action of the SpineJack® system relative to other implant devices (including BKP and the Kiva® system) contained important inaccuracies, including with regard to the claims that the SpineJack® system acts uniquely to achieve craniocaudal expansion, bilateral load support, and lift pressure >500 Newtons. The commenters stated that BKP does offer craniocaudal expansion while creating a void for safer cement fill. Furthermore, with respect to bilateral load support, according to the commenters, BKP has been offered since 1998 as a bilateral procedure option to maximize lift potential and reduce stress exerted on endplates. The commenters went on to explain that BKP provides bilateral symmetric load support to fractured endplates by providing a larger surface area when restoring height. Finally, the commenters asserted that several of the commenter's claims of superiority for the SpineJack® system were misleading, and furthermore that the newest generation of BKP implants is capable of inflating to 700 psi and generating a lift force of 1200 Newtons.

Another commenter made a different substantial similarity argument, with regard to the SpineJack® system and the Kiva® system. The commenter asserted that both the Kiva® system and SpineJack® systems use a similar mechanism of action (mechanical lift) to achieve a therapeutic outcome (reducing osteoporotic VCFs). The commenter noted that although the way the implant provides mechanical expansion within the vertebral body is different between the Kiva® and SpineJack® systems, both processes still qualify as mechanical expansion. The commenter described several other functional similarities in regard to the effect achieved by the Kiva® and SpineJack® systems, and further pointed out that the Kiva® system served as the predicate device for the SpineJack® system, with regard to the FDA 510(k) clearance process for the SpineJack® system. On this basis, the commenter asserted that the Kiva® and the SpineJack® system are substantially similar technologies.

One commenter expressed their general belief that the SpineJack® system meets the new technology add-on payment newness criterion because it utilizes a distinct mechanism of action, especially in comparison to the mechanisms of action utilized by the Kiva® system and balloon kyphopasty.

Response: We thank the commenters for their input and technical comments with regard to the SpineJack® system and the newness criterion. We note that some of these comments rest on conflicting factual assertions made by commenters and the applicant, which we are unable directly to resolve. After consideration of the comments received, however, we believe that the physical construction and mechanism of action by which the SpineJack® system implant exerts a lift force is mechanically different from either the Kiva® system (coil) implant, or from the inflation mechanism of a BKP implant. In our view, these differences support that the SpineJack® system does not use the same or similar mechanism of action to achieve a therapeutic outcome and therefore is not substantially similar to prior technology.

After consideration of the public comments we received and information submitted by the applicant as part of its FY 2021 new technology add-on payment application for the SpineJack® system, as discussed in the proposed rule (85 FR 32656) and previously in this final rule, we believe that the SpineJack® system has a unique mechanism of action in the treatment of patients with osteoporotic VCFs. Therefore, we believe that the SpineJack® system is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence following the approval of the SpineJack® system by the FDA, on the date when it became commercially available on the U.S. market, which was October 11, 2018.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2018 MedPAR file for inpatient hospital claims that reported the following ICD–10–PCS procedure codes: 0PS43ZZ (Reposition thoracic vertebra, percutaneous approach) in combination with 0PU43JZ (Supplement thoracic vertebra with synthetic substitute, percutaneous approach) and 0QS03ZZ (Reposition lumbar vertebra, percutaneous approach) in combination with 0QU03JZ (Supplement lumbar vertebra with synthetic substitute, percutaneous approach). According to the applicant, the results included cases involving BKP procedures. This resulted in 15,352 cases spanning approximately 130 MS–DRGs, with approximately 77 percent of those cases (n=11,841) mapping to the following top 6 MS–DRGs:

MS-DRG	MS-DRG Title
MS–DRG 477	Biopsies of Musculoskeletal System and Connective Tissue with MCC
MS–DRG 478	Biopsies of Musculoskeletal System and Connective Tissue with CC
MS–DRG 479	Biopsies of Musculoskeletal System and Connective Tissue without CC/MCC
MS-DRG 515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC
MS–DRG 516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC
MS-DRG 517	Other Musculoskeletal System and Connective Tissue O.R. Procedures without CC/MCC

The applicant performed two separate analyses with regard to the cost criterion, one based on 100 percent of the claims reporting the specified ICD–10–PCS procedure codes, and the second based on the 77 percent of claims mapping to the top six MS–DRGs.

The applicant used the following methodology for both analyses. The applicant first removed the charges for the prior technology being replaced by the SpineJack® system. The applicant explained that it estimated charges associated with the prior technology as 50 percent of the charges associated with the category Medical Surgical Supply Charge Amount (which included revenue centers 027x). The applicant stated that use of the SpineJack® system would replace some but not all of the device charges included in these claims, as some currently used medical and surgical supplies and devices would still be required for patients during their hospital stay, even after substituting the SpineJack® system for BKP and other surgical interventions. The applicant stated that it was unable to determine a more specific percentage for the appropriate amount of prior medical and surgical supply charges to remove from the relevant patient claims, but asserted that removing 50 percent of the charges was a conservative approach for calculation purposes. The applicant then standardized the charges and inflated the charges from FY 2018 to FY 2020. The applicant reported using an inflation factor of 11.1 percent, as published in the FY 2020 IPPS final rule (84 FR 42629).

The applicant then calculated and added the charges for the SpineJack® system technology by taking the estimated per patient cost of the device, and converting it to a charge by dividing the costs by the national average CCR (cost-to-charge ratio) of 0.299 for implantable devices from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179).

We stated in the proposed rule that in the analysis based on 100 percent of claims, the applicant computed a final inflated average case-weighted standardized charge per case of $108,760, as compared to an average case-weighted threshold amount of $77,395. In the analysis based on 77 percent of claims from only the top six MS–DRGs, the applicant computed a final inflated average case-weighted standardized charge per case of $92,904, as compared to an average case-weighted threshold amount of $72,273.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both analyses described previously, the applicant asserted that the technology meets the cost criterion. We invited public comments on whether the SpineJack® system meets the cost criterion.

Comment: The applicant offered a minor typographic correction in regard to the charge threshold analysis that was included in the proposed rule for the SpineJack® system. The applicant explained that in its new technology add-on payment application submission for the SpineJack® system, the inflated case-weighted standardized charge per case was reported as $108,670 for the analysis based on 100 percent of claims. The applicant noted that a transposition error was made in the proposed rule,

such that this figure was incorrectly reported as $108,760. The applicant concluded that the difference between these figures is negligible and does not impact the result of the average case-weighted standardized charge per case exceeding the average case-weighted threshold amount. Therefore, the applicant maintained that the SpineJack® system does meet the cost criterion.

Response: We thank the applicant for this correction and clarification with regard to the cost analysis for the SpineJack® system.

Comment: We received comments that were not directly related to the cost analysis, including that the different mechanism of action, time, and expertise involved in the use of the SpineJack® system uses warrants a separate billable code.We also received comments questioning the costs associated with the SpineJack® system, including that the estimated $100,000 cost per case appears high compared to the approximately $3,500 cost of other treatment options like kyphoplasty.

Response: We appreciate the commenters' feedback. We also note that proposals to create, delete, or revise codes under the ICD–10–PCS structure are referred to the ICD–10 Coordination and Maintenance Committee. The decisions of this committee are independent from any decision for new technology add on payments.

After consideration of the public comments we received and based on the information included in the applicant's new technology add-on payment application, we believe that the SpineJack® system meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the treatment of osteoporotic vertebral compression fracture (VCF) patients with the SpineJack® system represents a substantial clinical improvement over existing technologies because clinical research supports that it reduces future interventions, hospitalizations, and physician visits through a decrease in adjacent level fractures (ALFs), which the applicant asserted are clinically significant adverse events associated with osteoporotic VCF. The applicant also asserted that treatment with the SpineJack® system greatly reduces pain scores and pain medication use when compared to BKP, which the applicant stated is the current gold standard in vertebral augmentation (VA) treatment. The applicant submitted eight studies to support that its technology represents a substantial clinical improvement over existing technologies.

The applicant explained that the SpineJack® system has been available for the treatment of patients with osteoporotic VCFs for over 10 years in Europe. The applicant explained that, as a result, the SpineJack® system implant has been extensively studied, and claims from smaller studies are supported by the results from a recent, larger prospective, randomized study known as the SAKOS (SpineJack® versus Kyphoplasty in Osteoporotic Patients) study. The applicant cited the SAKOS study [318] in support of multiple clinical improvement claims. The applicant explained that the SAKOS study was the pivotal trial conducted in support of the FDA 510(k) clearance for the SpineJack® system and that the intent of the study was to compare the safety and effectiveness of the SpineJack® system with the KyphX Xpander Inflatable Bone Tamp (BKP) for treatment of patients with painful osteoporotic VCFs in order to establish a non-inferiority finding for use of the SpineJack® system versus balloon kyphoplasty procedure (BKP).

The SAKOS study is a prospective, international, randomized, non-inferiority study comparing a titanium implantable vertebral augmentation device (TIVAD), the SpineJack® system, versus BKP in the reduction of vertebral compression fractures with a 12-month follow-up. The primary endpoint was a 12-month responder rate based on a composite of three components: (1) Reduction in VCF fracture-related pain at 12 months from baseline by >20 mm as measured by a 100-mm Visual Analog Scale (VAS) measure, (2) maintenance or functional improvement of the Oswestry Disability Index (ODI) score at 12 months from baseline, and (3) absence of device-related adverse events or symptomatic cement extravasation requiring surgical reintervention or retreatment at the index level. If the primary composite endpoint was successful, a fourth component (absence of ALF) was added to the three primary components for further analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. According to the applicant, freedom from ALFs and midline VB height restoration were two additional superiority measures that were tested. According to the SAKOS study, secondary clinical outcomes included changes from baseline in back pain intensity, ODI score, EuroQol 5-domain (EQ–5D) index score (to evaluate quality of life), EQ–VAS score, ambulatory status, analgesic consumption, and length of hospital stay. Radiographic endpoints included restoration of vertebral body height (mm), and Cobb angle at each follow-up visit. Adverse events (AEs) were recorded throughout the study period. The applicant explained that researchers did not blind the treating physicians or patients, so each group was aware of the treatment allocation prior to the procedure; however, the three independent radiologists that performed the radiographic reviews were blinded to the personal data of the patients, study timepoints and results of the study.

The SAKOS study recruited patients from 13 hospitals across 5 European countries and randomized 152 patients with osteoporotic vertebral compression fractures (OVCFs) (1:1) to either the SpineJack® system or BKP procedures. Specifically, patients were considered eligible for inclusion if they met a number of criteria, including (1) at least 50 years of age, (2) had radiographic evidence of one or two painful VCF between T7 and L4, aged less than 3 month, due to osteoporosis, (3) fracture(s) that showed loss of height in the anterior, middle, or posterior third of the VB ≥15% but ≤40%, and (4) patient failed conservative medical therapy, defined as either having a VAS back pain score of ≥50 mm at 6 weeks after initiation of fracture care or a VAS pain score of ≥70% mm at 2 weeks after initiation of fracture care. Eleven of the originally recruited patients were subsequently excluded from surgery (9 randomized to the SpineJack® system and 2 to BKP). A total of 141 patients underwent surgery, and 126 patients completed the 12-month follow-up period (61 TIVAD and 65 BKP). The applicant contended that despite the SAKOS study being completed outside the U.S., results are applicable to the Medicare patient population, noting that 82 percent (116 of 141) of the patients in the SAKOS trial that received treatment (the SpineJack® system or BKP) were age 65 or older.

The applicant explained further that the FDA evaluated the applicability of the SAKOS clinical data to the U.S. population and FDA concluded that although the SAKOS study was performed in Europe, the final study demographics were very similar to what has been reported in the literature for U.S.-based studies of BKP. The applicant also explained that FDA determined that the data was acceptable

[318] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study),'' The Spine Journal, 2019, vol. 19(11), pp. 1782–1795.

for the SpineJack® system 510(k) clearance including two clinical superiority claims versus BKP.

The SAKOS study reported that analysis on the intent to treat population using the observed case method resulted in a 12-month responder rate of 89.8 percent and 87.3 percent, for the SpineJack® system and BKP respectively (p=0.0016). The additional composite endpoint analyzed in observed cases resulted in a higher responder rate for the SpineJack® system compared to BKP at both 6 months (88.1% vs. 60.9%; p<0.0001) and 12 months (79.7% vs. 59.3%; p<0.0001). Midline VB height restoration, tested for superiority using a *t* test with one-sided 2.5 percent alpha in the ITT population, was greater with the SpineJack® system than BKP at 6 months (1.14±2.61 mm vs 0.31±2.22 mm; p=0.0246) and at 12 months (1.31±2.58 mm vs. 0.10±2.23 mm; p=0.0035), with similar results in the per protocol (PP) population.

Also, according to the SAKOS study, decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021). At 12 months, the difference in pain intensity was no longer statistically significant between the groups, and pain intensity at 5 days post-surgery was not statistically different between the groups. The SAKOS study publication also reported that at each timepoint, the percentage of patients with reduction in pain intensity >20 mm was ≥90% in the SpineJack® system group and ≥80% in the BKP group, with a statistically significant difference in favor of SpineJack® at 1 month post-procedure (93.8% vs 81.4%; p=0.03). The study also reported—(1) no statistically significant difference in disability (ODI score) between groups during the follow-up period, although there was a numerically greater improvement in the SpineJack® system group at most time points; (2) at each time point, the percentage of patients with maintenance or improvement in functional capacity was at or close to 100 percent; and (3) in both groups, a clear and progressive improvement in quality of life was observed throughout the 1-year follow-up period without any statistically significant between-group differences.

In the SAKOS study, both groups had similar proportions of VCFs with cement extravasation outside the treated VB (47.3% for TIVAD, 41.0% for BKP; p=0.436). No symptoms of cement leakage were reported. The SAKOS study also reported that the BKP group had a rate of adjacent fractures more than double the SpineJack® system group (27.3% vs. 12.9%; p=0.043). The SAKOS study also reported that the BKP group had a rate of non-adjacent subsequent thoracic fractures nearly 3 times higher than the SpineJack® system group (21.9% vs. 7.4%) (a p-value was not reported for this result). The most common AEs reported over the study period were back pain (11.8 percent with the SpineJack® system, 9.6 percent with BKP), new lumbar vertebral fractures (11.8 percent with the SpineJack® system, 12.3 percent with BKP), and new thoracic vertebral fractures (7.4 percent with the SpineJack® system, 21.9 percent with BKP). The most frequent SAEs were lumbar vertebral fractures (8.8 percent with the SpineJack® system; 6.8 percent with BKP) and thoracic vertebral fractures (5.9 percent with the SpineJack® system, 9.6 percent with BKP). We also note that the length of hospital stay (in days) for osteoporotic VCF patients treated in the SAKOS trial was 3.8 ± 3.6 days for the SpineJack® system group and 3.3 ±2.4 days for the BKP group (p=0.926, Wilcoxon test).

The applicant also submitted seven additional studies, which are described in more detail in this section, related to the applicant's specific assertions regarding substantial clinical improvement.

As stated previously, the applicant asserted that the SpineJack® system represents a substantial clinical improvement over existing technologies because it will reduce future interventions, hospitalizations, and physician visits through a decrease in ALFs. The applicant explained that ALFs are considered clinically significant adverse events associated with osteoporotic VCFs, citing studies by Lindsay et al.[319] and Ross et al.[320] The applicant explained that these studies reported, respectively, that having one or more VCFs (irrespective of bone density) led to a 5-fold increase in the patient's risk of developing another vertebral fracture, and the presence of two or more VCFs at baseline increased the risk of ALF by 12-fold. The applicant asserted that analysis of the additional composite endpoint in the SAKOS study demonstrated statistical superiority of the SpineJack® system over BKP (p<0.0001) for freedom from ALFs at both 6 months (88.1 percent vs. 60.9 percent) and 12 months (79.7 percent vs. 59.3 percent) post-procedure. The applicant noted that the results were similar on both the intent to treat and PP patient populations. In addition, the applicant asserted the SpineJack® system represents a substantial clinical improvement because in the SAKOS study, compared to patients treated with the SpineJack® system, BKP-treated patients had more than double the rate of ALFs (27.3 percent vs. 12.9 percent; p=0.043) and almost triple the rate of non-adjacent thoracic VCFs (21.9 percent vs. 7.4 percent).

The applicant also asserted superiority with respect to mid-vertebral body height restoration with the SpineJack® system. The applicant explained that historical treatments of osteoporotic VCFs have focused on anterior VB height restoration and kyphotic Cobb angle correction; however, research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs.[321]

According to the applicant, the depression of the mid-vertebral endplate leads to decreased mechanics of the spinal column by transferring the person's weight to the anterior wall of the level adjacent to the fracture, and as a result the anterior wall is the most common location for ALFs. The applicant further asserted that by restoring the entire fracture, including mid-VB height, the vertebral disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs.[322] The applicant stated that the SpineJack® system showed superiority over BKP with regard to midline VB height restoration at both 6 and 12 months, pointing to the SAKOS study results in the intent to treat population at 6 months (1.14±2.61 mm vs 0.31±2.22 mm; p=0.0246) and 12 months (1.31±2.58 mm vs. 0.10±2.23 mm; p=0.0035) post-procedure. The applicant noted that similar results were also observed in the PP population (134 patients in the intent-to-treat population without any major protocol deviations).

The applicant also provided two prospective studies, a retrospective study, and two cadaveric studies in

[319] Lindsay R. et al., ''Risk of new vertebral fracture in the year following a fracture,'' Journal of the American Medical Association, 2001, vol. 285(3), pp. 320–323.

[320] Ross P. et al., Pre-existing fractures and bone mass predict vertebral fracture incidence in women. Annals of Internal Medicine. 1991, vol. 114(11), pp. 919–923.

[321] Lin J et al. Better height restoration, greater kyphosis correction, and fewer refractures of cemented vertebrae by using an intravertebral reduction device: A 1-year follow-up study. World Neurosurgery. 2016; 90:391–396.

[322] Tzermiadianos M., et al., ''Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture,'' European Spine Journal, 2008, vol. 17(11), pp. 1522–1530.

support of its assertions regarding superior VB height restoration. The applicant stated that in a prospective comparative study by Noriega D., et al.,[323] VB height restoration outcomes utilizing the SpineJack® system were durable out to 3 years. This study was a safety and clinical performance pilot that randomized 30 patients with painful osteoporotic vertebral compression fractures to the SpineJack® system (n=15) or BKP (n=15).[324] Twenty-eight patients completed the 3-year study (14 in each group). The clinical endpoints of analgesic consumption, back pain intensity, ODI, and quality of life were recorded preoperatively and through 36-months post-surgery.[325] Spine X-rays were also taken 48 hours prior to the procedure and at 5 days, 6, 12, and 36 months post-surgery.[326] The applicant explained that over the 3-year follow-up period, VB height restoration and kyphosis correction was better compared to BKP, specifically that VB height restoration and kyphotic correction was still evident at 36 months with a greater mean correction of anterior VB height ($10 \pm 13\%$ vs $2 \pm 8\%$ for BKP, p=0.007) and midline VB height ($10 \pm 11\%$ vs $3 \pm 7\%$ for BKP, p=0.034), while there was a larger correction of the VB angle ($-4.97° \pm 5.06°$ vs $0.42° \pm 3.43°$; p=0.003) for the SpineJack® system group. The applicant stated that this study shows superiority with regards to VB height restoration.

The applicant asserted that Arabmotlagh M., et al., also supported superiority with regard to VB height restoration. Arabmotlagh M., et al. reported a single-arm observational case series of the SpineJack® system. They enrolled 42 patients with osteoporotic vertebral compression fracture of the thoracolumbar, who were considered for kyphoplasty, 31 of whom completed the clinical and radiological evaluations up to 12 months after the procedure.[327] According to materials provided by the applicant, the purpose of the study was to evaluate the efficacy of kyphoplasty with the SpineJack® system to correct the kyphotic deformity and to analyze parameters affecting the restoration and maintenance of spinal alignment. The applicant explained that the mean VB height calculated prior to fracture was 2.8 cm (standard deviation (SD) of 0.47), which decreased to 1.5 cm (SD of 0.59) after the fracture. According to the applicant, following the procedure performed with the SpineJack® system device, the VB height significantly increased to 1.9 cm (SD of 0.64; p<0.01), but was reduced to 1.8 cm (SD of 0.61; p<0.01) at 12 months post-procedure. We note that according to Arabmotlagh M., et al. (2018), these results were specifically for mean anterior VB height. The study does not appear to report results for midline VB height.[328] The applicant also stated that the mean kyphotic angle (KA) calculated prior to fracture was -1° (SD of 5.8), which increased to 13.4° (SD of 8.1) after the fracture. The applicant also stated that following the procedure performed with the SpineJack® system device, KA significantly decreased to 10.8° (SD of 9.1; p<0.01); however, KA correction was lost at 12 months post-procedure with an increase to 13.3° (SD of 9.5; p<0.01).

The applicant provided a Lin et al., retrospective study of 75 patients that compared radiologic and clinical outcomes of kyphoplasty with the SpineJack® system to vertebroplasty (VP) in treating osteoporotic vertebral compression fractures to support its assertions regarding superiority with regard to midline VB height restoration.[329] The applicant stated that the radiologic outcomes from this study were: (1) The mean KA and mean KA restoration was more efficient after the SpineJack® system than VP at all time points (up to 1 year), except for mean KA observed postoperatively at 1 week; and (2) the mean middle VB heights and mean VB height restoration was more favorable after the SpineJack® system than VP.[330] We note that this study did not compare the SpineJack® system to BKP, which the applicant stated is the gold-standard in vertebral augmentation.

In the two cadaveric studies, Kruger A., et al. (2013) and Kruger A., et al. (2015), wedge compression fractures were created in human cadaveric vertebrae by a material testing machine and the axial load was increased until the height of the anterior edge of the VB was reduced by 40 percent.[331] The VBs were fixed in a clamp and loaded with 100 N in a custom made device. In Kruger A., et al. (2013), vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane in 36 human cadaveric vertebrae pre- and post-fracture as well as after treatment and loading in (27 vertebrae were treated with the SpineJack® system with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with BKP). In Kruger A., et al. (2015), anterior, central, and posterior height as well as the Beck index were measured in 24 vertebral bodies pre-fracture and post-fracture as well as after treatment (twelve treated with the SpineJack® system and twelve treated with BKP).

The applicant asserted that Kruger A., et al. (2013) showed superiority on VB height restoration and height maintenance, and summarized that: (1) Height restoration was significantly better for the SpineJack® system group compared to BKP; (2) height maintenance was dependent on the cement volume used; and (3) the group with the SpineJack® system without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.[332]

The applicant asserted that Kruger A., et al. (2015) showed superiority on VB height restoration, because the height restoration was significantly better in the SpineJack® system group compared with the BKP group. The applicant explained that the clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.[333]

The applicant also asserted that use of the SpineJack® system represents a substantial clinical improvement with respect to pain relief. According to the applicant, pain is the first and most prominent symptom associated with osteoporotic VCFs, which drives many elderly patients to seek hospital treatment and negatively impacts on

[323] Noriega D., et al., ''Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: A pilot, monocentric, investigator-initiated study,'' Osteoporosis International, 2019, vol. 30, pp. 637–645.

[324] Ibid.

[325] Ibid.

[326] Ibid.

[327] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' Journal of Orthopaedic Research, 2018. Doi: 10.1002.jor.24180.

[328] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' Journal of Orthopaedic Research, 2018. Doi: 10.1002.jor.24180.

[329] Lin J., et al., ''Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: A 1-Year Follow-up Study,'' World Neurosurg. 2016, vol. 60, pp. 391–396.

[330] Ibid.

[331] Kruger A., et al., ''Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used,'' Clinical Biomechanics, 2013, vol. 28, pp. 725–730; and Kruger A., et al., ''Height restoration of osteoporotic vertebral compression fractures using different intervertebral reduction devices: A cadaveric study,'' The Spine Journal, 2015, vol. 15, pp. 1092–1098.

[332] Ibid.

[333] Ibid.

their quality of life. The applicant provided the SAKOS randomized controlled study, a prospective consecutive observational study, and a retrospective case series to support its assertions regarding pain relief with the SpineJack® system.

The applicant cited the SAKOS trial for statistically significant greater pain relief achieved at 1 month and 6 months after surgery with the SpineJack® system. The applicant summarized that in the SAKOS trial (1) progressive improvement in pain relief was observed over the follow-up period in the SpineJack® system group only; (2) the decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021); and (3) at each time point, the percentage of patients with reduced pain intensity >20 mm was ≥90 percent in the SpineJack® system group and ≥80 percent in the BKP group, with a statistically significant difference in favor of the SpineJack® system at 1 month post-procedure (93.8% vs 81.5%; p=0.030). The applicant also noted that although continued pain score improvements were seen out to 1 year for patients treated with the SpineJack® system, the difference between the treatment groups did not meet statistical significance (p=0.061).

The applicant also explained that in the SAKOS study, at 5 days after surgery, there were significantly fewer patients taking central agent medications in the SpineJack® system implant-treated group as compared to those in the BKP-treated group (SJ 7.4% vs. BKP 21.9%, p=0.015). According to the applicant, central analgesic agents included medications such as non-steroidal anti-inflammatory drugs (NSTATEDS), salicylates, or opioid analgesics.

The applicant also cited a prospective consecutive observational study by Noriega D., et al. for statistically significant pain relief immediately after surgery and at both 6 and 12 months. Noriega D., et al. was a European multicenter, single-arm registry study that aimed to confirm the safety and clinical performance of the SpineJack® system for the treatment of vertebral compression fractures of traumatic origin (no comparison procedure).[334] The study enrolled 103 patients (median age: 61.6 years) with 108 VCFs due to trauma (n=81), or traumatic VCF with associated osteoporosis (n=22) who had the SpineJack® system procedure. Twenty-three patients withdrew from the study before the 12-month visit.

The study reported a significant improvement in back pain at 48 hours after the SpineJack® system procedure, with the mean VAS pain score decreasing from 6.6 ± 2.6 cm at baseline to 1.4 ± 1.3 cm (mean change: −5.2 ± 2.7 cm; p<0.001) (median relative decrease in pain intensity of 81.5 percent) for the total study population. Noriega D., et al. also reported that the improvement was maintained over the 12-month follow-up period and similar results were observed with both pure traumatic VCF and traumatic VCF in patients with osteoporosis. The traumatic VCF with osteoporosis sub-group had a mean change of −5.5 (SD=1.9) (median relative change of 81.0%) (p<0.001) at 48 hours post-surgery (n=22), and −5.7 (SD=2.3) mean change (90.3% median relative change) (p<0.001) at 12 months (n=16). The applicant stated that this study supported a claim of statistically significant pain relief immediately after surgery and at both 6 and 12 months.

The applicant summarized that (1) pain relief and improvements in pain scores were statistically significant immediately after treatment (48–72 hours) and at 6 and 12 months following surgery (p<0.001); and (2) the mean improvement between baseline and at 48–72 hours after the procedure (n=31) was −4.6 (2.6) (p<0.001), while the mean improvement between baseline and at the 12-month follow-up (n=22) was −6.0 (3.4) (p<0.001). We note that Noriega D., et al. did not report results for 6 months (although it does include results for 3 months versus baseline) and does not include the results of mean improvement stated by the applicant.[335] It is also unclear if the applicant intended to rely on the overall results of the study or the subgroup of traumatic VCF with osteoporosis.

The applicant also cited a retrospective case series, Renaud C., et al., for statistically significant pain relief after surgery with the SpineJack® system. Renaud C., et al., included 77 patients with a mean age of 60.9 years and 83 VCFs (51 due to trauma and 32 to osteoporosis) treated with 164 SpineJack® system devices (no comparison procedure).[336] The applicant summarized that—(1) pain relief was statistically significant (p<0.001), with a pain score decrease from 7.9 pre-operatively to 1.8 at 1 month after the procedure; (2) the pain score improvement was 77 percent at hospital discharge and gradually increased to 86 percent after 1 year following surgery; and (3) the study outcomes demonstrated that the SpineJack® system provided both immediate and long-lasting pain relief.

After reviewing the information submitted by the applicant as part of its FY 2021 new technology add-on payment application for the SpineJack® system, we noted that the results of the SAKOS trial did not appear to have been corroborated in any other randomized controlled study. Additionally, although the applicant stated that BKP is the gold standard in VA, we noted that there appeared to be a lack of data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant (the Kiva® system), particularly since the PEEK coiled system was considered the predicate device for the SpineJack® system FDA 510(k) clearance. Furthermore, we noted that there appeared to be a lack of data comparing the SpineJack® system to conservative medical therapy, although there was an active study posted on *clinicaltrials.gov* comparing the SpineJack® system to conservative orthopedic management, the latter consisting of brace and pain medication in acute stable traumatic vertebral fractures in subjects aged 18 to 60 years old. The *clinicaltrials.gov* entry indicated that findings should be forthcoming in 2020.

Additionally, we noted that two recent systematic reviews of the management of vertebral compression fracture (Buchbinder et al. for Cochrane (2018), Ebeling et al. (2019) for the American Society for Bone and Mineral Research (ASBMR)) did not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management.[337] The ASBMR recommended more rigorous study of treatment options including ''larger sample sizes, inclusion of a placebo control and more data on serious AEs (adverse events).'' We invited public comment on whether

[334] Noriega D., et al., ''Clinical performance and safety of 108 SpineJack implantations: 1-year results of a prospective multicentre single arm registry study.'' BioMed Research International. 2015, 173872.

[335] Ibid.

[336] Renaud C., ''Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack: Technical note and outcomes in 77 consecutive patients.'' Orthopaedics & Traumatology: Surgery & Research, 2015, vol. 101, pp. 857–859.

[337] Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., ''Percutaneous vertebroplasty for osteoporotic vertebral compression fracture,'' Cochrane Database Syst Rev. 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Bouxsein M.L., ''The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report.'' J Bone Miner Res., 2019, vol. 34(1), pp. 3–21.

the SpineJack® system meets the substantial clinical improvement criterion.

Comment: The applicant submitted comments in response to CMS's concerns in the FY 2021 IPPS/LTCH PPS proposed rule regarding whether the SpineJack® system meets the substantial clinical improvement criterion.

With respect to the FY 2021 IPPS/LTCH PPS proposed rule concern that recent systematic reviews of the management of VCF for Cochrane and ASBMR did not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management, the applicant responded that the latest clinical evidence and a policy statement from the International Society for the Advancement of Spine Surgery (ISASS) do provide robust support for the use of vertebral augmentation (VA) over non-surgical management (NSM) in the treatment of osteoporotic VCFs.

According to the applicant, a recent systematic review and meta-analysis by Beall et al. (2018) [338] included 25 prospective studies (either level 1 or level 2 evidence), comparing vertebral augmentation over NSM for the treatment of thoracic and lumbar VCFs. Again according to the applicant, the Beall meta-analysis reportedly found that both balloon kyphoplasty (BKP)-treated patients and vertebroplasty (VP)-treated patients had significantly greater pain reduction over those treated with NSM.

Relatedly, the applicant pointed to a policy statement released by the ISASS in 2018, the medical society concluded that, based upon the body of clinical evidence available for the international spine community, it could ''confidently advocate that there is strong support for vertebral augmentation in the treatment of symptomatic VCFs.''

The applicant also pointed to recent Local Coverage Determinations on percutaneous vertebral augmentation (PVA) for osteoporotic VCF, published by the seven regional Medicare Administrative Contractors (MACs). According to the applicant, the LCD for Noridian in particular stated that the preponderance of evidence (including empirical studies) favors consideration of PVA in select osteoporotic VCF patients.

Finally, the applicant asserted that the SAKOS trial for the SpineJack® system was specifically designed to address the ASBMR recommendations for more rigorous study of VCF treatments, through larger study sample sizes, inclusion of a placebo control, and more data on serious adverse events.

With respect to the FY 2021 IPPS/LTCH PPS proposed rule concern that the results of the SAKOS trial have not been corroborated in any other randomized controlled trial, and regarding the lack of data comparing the SpineJack® system to technologies other than BKP (like the Kiva® system PEEK coiled implant), the applicant responded that multiple randomized trials are often not conducted to corroborate level one evidence that has been published in a peer-reviewed journal, such as the SAKOS trial data for the SpineJack® system.

The applicant also stated that at least 16 supporting journal articles had been cited in its new technology add-on payment application, highlighting the significant clinical benefit of the SpineJack® system for osteoporotic VCFs.

With regard to the Kiva® system, the applicant stated that the Kiva® system was found to be non-inferior to BKP, but not superior to BKP, in the Kiva® system's own randomized clinical trial study. According to the applicant, because the Kiva® system was not found superior to BKP, has not been widely adopted in the United States, and because the SpineJack® system was found superior to BKP on some outcomes in the SAKOS trial, the applicant concluded that the Kiva® system was not an appropriate clinical comparator for study.

With respect to the FY 2021 IPPS/LTCH PPS proposed rule concern that there is a lack of data comparing the SpineJack® system to conservative medical therapy (or non-surgical management, NSM), the applicant asserted that substantial clinical evidence may be found throughout the published medical literature on improved outcomes with BKP compared to NSM when treating patients with osteoporotic VCFs. According to the applicant, examples of publications that highlight the benefits of BKP treatment include those from the FREE (Fracture Reduction Evaluation) trial, which describe rapid pain reduction and clinical improvements in function and quality of life, as well as radiologic improvements in VB height and kyphotic angulation, among BKP-treated patients vs. NSM-treated patients.[339] [340] [341] A publication from the EVOLVE trial also illustrates significant improvements in pain scores, functional capability, and quality of life among osteoporotic patients treated with BKP.[342]

The applicant then cited to several additional studies showing mortality and survival benefits associated with BKP and VP procedures in the treatment of VCF, as compared to NSM. According to the applicant, based upon the body of evidence available, the use of NSM as a comparator treatment to the SpineJack® system for a new clinical study would not be in the best interest of osteoporotic VCF patients. This is primarily due to the increased risk of morbidity and mortality that has been reported in this patient population, particularly among the elderly.

With regard to the active study noted by CMS listed on *ClinicalTrials.gov* (NCT02657265) that compares the SpineJack® system to conservative orthopedic management, the applicant noted that this is an ongoing trial in Europe that has been designed to treat patients with acute traumatic VCFs, rather than osteoporotic VCFs. Patients enrolled in this study are between the ages of 18 to 60, which reflects the younger age demographic found among traumatic VCF patients. Since patients 65 years and older are not included in the study population, the results from this European trial will not be applicable to the Medicare patient population with osteoporotic VCFs. Finally, the applicant provided additional clarifications or minor corrections with regard to several specific studies that were cited in the new technology add-on payment application, for which CMS noted an interpretive question or concern. The clarifications provided by the applicant addressed each of Lin et al. (2016), Arabmotlagh et al. (2018), and Noriega et al. (2015). The applicant also requested the correction of a minor typographical error in the FY 2021 IPPS proposed rule regarding the SAKOS study results for one of the values concerning VB height restoration at 12

[338] Beall D et al., ''Review of vertebral augmentation: An updated meta-analysis of the effectiveness,'' International Journal of Spine Surgery, 2018, vol. 12(3), pp. 295–321.

[339] Wardlaw D et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): A randomised controlled trial. Lancet. 2009; 373(9668):1016–1024.

[340] Boonen S et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. Journal of Bone and Mineral Research. 2011; 26(7):1627–1637.

[341] Van Meirhaeghe J et al. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: Vertebral body kyphosis correction and surgical parameters. Spine. 2013; 38(12):971–983.

[342] Beall D et al. Prospective and multicenter evaluation of outcomes for quality of life and activities of daily living for balloon kyphoplasty in the treatment of vertebral compression fractures: The EVOLVE trial. Neurosurgery. 2019; 84(1):169–178.

months. Specifically, according to the applicant, for the midline VB height restoration reported at 12 months for the SpineJack® system compared to BKP in the SAKOS trial, an inadvertent error appears in the standard deviation value for the BKP data reported in the proposed rule. The applicant stated this value should be revised as follows to match the SAKOS trial publication: ''12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.34 mm; p=0.0035) post-procedure.''

One commenter who is a manufacturer of BKP implants made several criticisms of the evidence put forward by the applicant, with regard to whether the SpineJack® system meets the substantial clinical improvement criterion. The commenter emphasized that although the applicant cited the SAKOS study as the basis for concluding that the SpineJack® system meets the substantial clinical improvement criterion, the SAKOS study compared the SpineJack® system to older BKP technology (KyphX), rather than to the most current BKP technology available at the time of the study (Xpander II and Express II). According to the commenter, these second-generation balloons have been available since 2014, generate lift force in excess of 1200 Newtons, and are the only BKP products indicated for the cement resistance technique, whereby one bone tamp is left in place during cement injection and curing to maximize height restoration in a collapsed vertebral body. The commenter suggested that if the SAKOS study had compared the SpineJack® system to these second-generation BKP implants, then the SpineJack® system might not have demonstrated superior performance on secondary outcome measures.

The commenter also offered several additional criticisms of the SAKOS study. The commenter pointed out that the SAKOS study design did not involve an even distribution of the spine levels treated across study arms, and that it is possible that a difference in the levels treated could have contributed to the reduction of ALFs in the SpineJack® system group. The commenter asserted that the vertebral levels T11–L1 are commonly known for higher number of fractures, and that these spinal segments had 14 more levels treated with BKP than with the SpineJack® system in the SAKOS study. According to the commenter, further analysis would be needed to determine if the location of fractures had an effect on the occurrence of ALFs between the two study arms in SAKOS. The commenter also pointed out that it was unclear whether there was any difference in the two treatment groups' bone density metrics, as this was not disclosed in the SAKOS study.

The commenter went on to emphasize that the clinical comparison in the SAKOS study demonstrated the SpineJack® system was non-inferior to BKP at the time of the primary endpoint (12 months); however, there was no significant difference between groups in pain intensity visual analog scale (VAS) score at the final time point, and no difference in Oswestry Disability Index (ODI) or the EQ–5D health status questionnaire at any time point during the study. The commenter acknowledged that SAKOS demonstrated superiority for the SpineJack® system for mid-vertebral height restoration, but emphasized that measures of anterior height, posterior height, and cobb angle showed no difference across the study arms, within the secondary endpoints. The commenter also observed that the SAKOS study showed a similar number of adverse events between study arms, with the SpineJack® system population seeing a higher percentage of serious adverse events.

Finally, the commenter disputed the applicant's assertion that vertebral augmentation treatment with vertebroplasty may alleviate pain, but cannot restore vertebral body height or correct spinal deformity. The commenter likewise disputed the applicant's assertion that BKP attempts to restore vertebral body height, but the temporary correction obtained cannot be sustained over the long-term (85 FR 32656). In countering the applicant's assertions, the commenter referenced three published articles with empirical evidence regarding the impact of BKP on kyphotic angle and VB height restoration.[343] [344] [345]

Another commenter provided a detailed technical criticism of several aspects of the SAKOS trial, and asserted that the SpineJack® system does not meet the substantial clinical improvement criterion. This commenter also stated that the BKP arm of the SAKOS study used an older generation of balloon implants with less ability to deliver lift force and to improve VB height. The commenter asserted that in order to claim superiority for the SpineJack® system, the SAKOS trial should have used the newer generation balloon implants, and that the failure to do so calls into question the SAKOS findings of improved height restoration and reduced ALFs for the SpineJack® system.

The commenter also noted that the SAKOS study reported an exceedingly high 40% rate of disc space extravasation in the balloon kyphoplasty arm. The commenter disputed that this high rate of disc space extravasation is typical based on the literature on BKP, and the commenter cited to two BKP trials which found much lower rates of disc space extravasation.[346] [347] According to the commenter, the high rate of disc extravasation in the BKP arm of the SAKOS trial calls into question the claims that the SpineJack® system reduced the occurrence of ALFs, since disc extravasation has itself been shown to induce ALFs in other empirical studies. The commenter also suggested that the difference in ALFs across the two SAKOS study arms could also help to explain the finding of improved pain intensity scores for the SpineJack® system at different secondary time points.

The commenter offered several additional criticisms with regard to the SAKOS study, including that fractures in the T11–L1 junctional zone were not evenly distributed across study arms, and might have mediated the observed difference in the occurrence of ALFs. The commenter also raised questions about whether the degree of osteoporosis was held consistent across the SAKOS study arms, and whether the inclusion criteria for SAKOS (requiring an initial period of at least 6 weeks of conservative medical therapy) might make the study findings less applicable to the American Medicare population generally. The commenter challenged the applicant's assertion that BKP does not sustain VB height recovery over the long term, and the commenter provided several citations to empirical studies stating the contrary.[348] [349] [350] [351] [352] [353]

[343] Van Meirhaeghe JV, et al. 2013;38(12): 971–983.

[344] Dohm M, et al. Am J Neuroradiol. 2014;35:2227–2236.

[345] Bozkurt M, et al. Asian Spine J. 2014; 8(1):27–34.

[346] Wardlaw D, Cummings SR, Van Meirhaeghe J, Bastian L, Tillman JB, Ranstam J, Eastell R, Shabe P, Talmadge K, Boonen S. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): A randomised controlled trial. Lancet. 2009. PubMed PMID: 19246088.

[347] Beall DP, Chambers MR, Thomas S, Amburgy J, Webb JR, Goodman BS, et al. Prospective and multicenter evaluation of outcomes for quality of life and activities of daily living for balloon kyphoplasty in the treatment of vertebral compression fractures: The EVOLVE trial. *Neurosurg* 2019;84(1):169–178.

[348] Dohm M, Black C, Dacre A, Tillman JB, Fueredi G, KAVIAR Investigators. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. AJNR 2014;35:2227–36.

[349] Beall DP, Chambers MR, Thomas S, Amburgy J, Webb JR, Goodman BS, et al. Prospective and multicenter evaluation of outcomes for quality of

Continued

The commenter challenged the importance of the SAKOS finding of superiority for the SpineJack® system on mid-vertebral height restoration, and reiterated that the SAKOS study findings on measures of anterior VB height, posterior VB height, and Cobb Angle measurements showed no differences between the SpineJack® system and BKP.

The commenter further noted that the applicant only cited one study to support the statement that ''research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs,'' and the commenter asserted that the cited study does not actually support that statement.

The commenter concluded that the current medical standard for prevention of ALFs remains the Cobb angle and anterior VB height measurements. Finally, the commenter also challenged the applicant's assertion that ''by restoring the entire fracture, including mid-VB height, the vertebral disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs,'' based on results from a single cadaveric study.

Several commenters agreed that the SpineJack® system provides pain reduction based on their clinical experiences. Several commenters also agreed that patients are either pain-free or nearly pain-free based on their clinical experiences. One commenter agreed that the SpineJack® system would theoretically decrease pain based on the study provided. Several commenters believed that decreased pain enhances activities of daily living (ADLs) and overall quality of life for older patients, which may further reduce long term care resource consumption. Several commenters also expressed their belief that the pain reduction the SpineJack® system provides causes patients to require less opioid prescriptions for pain. The commenters cited both the inability of the older adult population to tolerate opioids, the abuse or dependency potential for patients, and potential for misuse by persons other than the prescribed as benefits of a reduction in opioid prescriptions written and dispensed.

Many commenters agreed that they have seen evidence of increased VB height restoration in their clinical experience, and many commenters believed based on their clinical experiences that the SpineJack® system is superior to other product options for these fractures. Commenters cited improved posture, sagittal alignment, improved pulmonary function, and/or better disc health. Several commenters also noted that the SpineJack® system is especially useful in certain subsets of patients, with commenters citing various subgroups including older patients, patients who have already experienced previous compression fractures, who have complex fractures, who have fractures under 3 months old, who have older fractures, who have greater than 25% vertebral body height loss, and/or who have mild to moderate retropulsion of the posterior endplate. Several commenters further noted that in their clinical experience the SpineJack® system requires less cement for stabilization, leading to less risk of cement leakage.

Many commenters believed that the SpineJack® system will reduce ALFs based on their clinical experience, or on review of the SAKOS study. A few commenters believed that the SpineJack® system allows patients to have increased posture correction and locomotion, and that, combined with the reduced ALFs, will lead to a higher quality of life in the future. Many commenters asserted that the SpineJack® system is their preferred treatment option generally.

One commenter believed that the literature regarding vertebral augmentation techniques is inconsistent because of multiple guidelines from various societies that are inconsistent with each other. The commenter believed this disagreement leads to variation in the methodology of research papers to evaluate this technique. The commenter asserted that as a result, the large Cochrane and ASBMR reviews are conglomerations of heterogeneous data which will invariably show no statistical difference.

A few commenters believed that conservative medical management as an option for patients with VCFs is no longer an accepted standard of care. One commenter stated the ASBMR view is inconsistent with multiple Medicare Administrative Contractor local coverage determinations, which indicate that earlier intervention in some patients is supported by the literature.

A few commenters believed that the SAKOS study was well designed despite the lack of a control arm, and supported its claims, including with regard to ALFs, VB height, and superior pain relief. One commenter believed that BKP was the correct comparator for the SAKOS study as the Kiva® system was unable to demonstrate improvement over BKP in a separate study.

Response: We appreciate all the comments received related to the SpineJack® system, and we have taken them into consideration in making our determination, including the applicant's submission of additional information to address the concerns presented in the proposed rule and the comments expressing concerns with the design and results of the SAKOS study.

After consideration of the public comments received, we believe that commenters have addressed our concerns regarding whether the SpineJack® system meets the substantial clinical improvement criterion and that the SpineJack® system represents a substantial clinical improvement over existing technologies based on the data received from commenters. The data provided from the commenters with clinical experience with vertebral augmentation procedures and the SpineJack® system which included improved pain, VB height restoration and ALF outcomes for patients with osteoporotic VCFs when compared with existing treatments demonstrates substantial clinical improvement.

After consideration of the public comments we received, we have determined that the SpineJack® system meets all of the criteria for approval for new technology add-on payments. Therefore, we are approving new technology add-on payments for the SpineJack® system for FY 2021. Cases involving the use of the SpineJack® system that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XNU0356 (Supplement lumbar vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6) and XNU4356 (Supplement thoracic vertebra with mechanically expandable (paired) synthetic substitute, percutaneous approach, new technology group 6).

In its application, the applicant estimated that the average cost of the SpineJack® system is $5,622.64 per patient. Under § 412.88(a)(2), we limit

life and activities of daily living for balloon kyphoplasty in the treatment of vertebral compression fractures: the EVOLVE trial. *Neurosurg* 2019;84(1):169–178.

[350] Morozumi M, Matsubara Y, Muramoto A, Morita Y, Ando K, Kobayashi K, Machino M, Ota K, Tanaka S, Kanbara S, Ito S, Ishiguro N, Imagama S. A Study of Risk Factors for Early-Onset Adjacent Vertebral Fractures After Kyphoplasty. Global Spine Journal 2019 10:1, 13–20.

[351] Van Meirhaeghe JV., Bastian L., Boonen S., et al. A Randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures. Spine 2013; 38(12): 971–983.

[352] Significantly Better Height Restoration vs. Unilateral BKP and VP ($p < 0.001$) Bozkurt M, et al. Asian Spine J. 2014; 8(1):27–34.

[353] Gu C., Brinjikji W., Evans A., et al. Outcomes of vertebroplasty compared with kyphoplasty: A systematic review and meta-analysis. J NeuroIntervent Surg. 2016 Jun;8(6):636–42.

new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of the SpineJack® system is $3,654.72 for FY 2021.

j. WavelinQ™ (4F) EndoAVF System

Becton Dickinson & Company (BD) submitted an application for new technology add-on payments for the WavelinQ™ (4F) EndoAVF System for FY 2021. According to the applicant, the predicate device, the WavelinQ™ (6F) EndoAVF System (formerly named the everlinQ endoAVF system) received FDA marketing authorization on June 22, 2018 for the indication of the creation of an arteriovenous fistula (AVF) using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. On February 6, 2019 the FDA cleared the WavelinQ™ (4F) EndoAVF System via its 510(k) (premarket notification). The WavelinQ™ 4F EndoAVF System is indicated for the creation of an AVF using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. It is our understanding that the WavelinQ™ (4F) EndoAVF System replaces the WavelinQ™ (6F) EndoAVF System. The applicant noted that it is applying for new technology add-on payments for the WavelinQ™ (4F) EndoAVF System and not the WavelinQ™ (6F) EndoAVF System. The applicant also noted that the WavelinQ™ (4F) EndoAVF System has been cleared to treat both the radial arteries and veins and the ulnar arteries and veins. Per the applicant, the only difference between the two technologies and their respective approvals is the size of the catheters (6F vs. 4F) and the expanded indication to treat the radial arteries and veins for the WavelinQ™ (4F) EndoAVF System.

Hemodialysis, a form of treatment for kidney failure patients, is a procedure that removes wastes, salts, and fluid from a patient's blood when the kidneys can no longer perform these functions. To receive dialysis, patients require a vascular access, such as an arteriovenous (AV) fistula, to connect to the dialysis machine.

The applicant asserted that Endovascular AV fistula creation with the WavelinQ™ (4F) EndoAVF System is achieved using flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy and includes vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), and venography (to fluoroscopically guide placement and alignment of the venous magnetic radiofrequency [RF] catheter), ultrasound, and final fistulogram to document AV fistula creation).

The applicant asserted that the following ICD–10–CM diagnosis codes are applicable to the WavelinQ™ (4F) EndoAVF System: N18.4 (Chronic kidney disease, stage 4), N18.5 (Chronic kidney disease, stage 5), and N18.6 (End stage renal disease). The applicant also asserted that the following ICD–10–PCS procedure codes identify cases involving use of the WavelinQ™ (4F) EndoAVF System: 03193ZF (Bypass right ulnar artery to lower arm vein, percutaneous approach), 031A3ZF (Bypass left ulnar artery to lower arm vein, percutaneous approach), 031B3ZF (Bypass right radial artery to lower arm vein, percutaneous approach), and 031C3ZF (Bypass left radial artery to lower arm vein, percutaneous approach).

As stated previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the WavelinQ™ (4F) EndoAVF System uses a different mechanism of action than any commercially available technology on the market for hemodialysis fistula creation. The applicant stated the WavelinQ™ (4F) EndoAVF System is not an open surgical approach, and that this is the first differentiating factor from previous methods used to create an arteriovenous fistula. The applicant also explained that WavelinQ™ (4F) EndoAVF System consists of flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy to create a communicating channel between the arterial and venous system via an endovascular approach. Additionally, the applicant explained that as part of the procedure, the WavelinQ™ (4F) EndoAVF System also requires vascular embolization of the brachial vein, fistulogram, angiography, venography, and ultrasound, as discussed above. The applicant asserted that in summary, the endovascular creation of an AV fistula using radiofrequency energy delivered through magnetic-guided catheters is a unique mechanism of action.

The applicant indicated the Ellipsys® Vascular Access System (Avenu Medical) has recently been granted marketing authorization by the FDA (January 25, 2019). The applicant asserted that while Ellipsys® is also an endovascular method of creating an AV fistula, there are several important points of differentiation between the two devices and their corresponding procedures. According to the applicant, there are different mechanisms of action, procedural processes, and anatomical locations of fistula creation as follows:

- *Fistula creation:* WavelinQ™ utilizes radiofrequency ablation; Ellipsys® utilizes thermal resistance (heat).
- *Embolization:* WavelinQ™ requires coil embolization of the brachial vein at the time of EndoAVF creation; Ellipsys® does not.
- *Guidance:* WavelinQ™ utilizes magnetic catheters to guide and align the location of the EndoAVF creation site and Ellipsys® does not have a mechanism for aligning the fistula creation site.
- *Fistula location:* WavelinQ™ offers two options for fistula creation compared to Ellipsys®: First, the WavelinQ™ can create a fistula between the concomitant ulnar artery and ulnar vein. According to the applicant, this is an unused vascular bed for traditional surgical fistula options which does not interfere with necessary blood flow for hemodialysis purposes, thus preserving all future surgical AV fistula options such as radiocephalic, brachiocephalic, and brachiobasilic fistulas. Second, the WavelinQ™ can create a fistula between the concomitant radial artery and radial vein. This method eliminates the ability to perform a future radiocephalic fistula. In comparison, the Ellipsys® device is only able to create a fistula from the proximal radial artery to the perforating vein, thus eliminating any future use of a radiocephalic fistula.
- *Access methods:* WavelinQ™ accesses both the arterial system and venous system and Ellipsys® utilizes only the venous system.
- *Imaging:* There are different methods of visualization in that WavelinQ™ uses including ultrasound and fluoroscopy, whereas Ellipsys® only uses ultrasound.
- *Subsequent procedures:* Ellipsys® requires a secondary balloon

angioplasty procedure at a later date, while WavelinQ™ does not.

• *Procedure Times and Complexity:* EndoAVF creation with WavelinQ™ is an 85-minute procedure, whereas EndoAVF creation with Ellipsys® is a 23-minute procedure, which the applicant states represents a marked difference in procedure complexities.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that its MS–DRG analysis showed that cases using the WavelinQ™ (4F) EndoAVF System will most often be mapped to MS–DRG 264 (Other Circulatory System O.R. Procedures), per the assignment of recently created ICD–10–PCS codes for endovascular fistula creation. The applicant anticipated that cases using the Ellipsys® Vascular Access System will also be frequently mapped to this MS–DRG as MS–DRG 264 is the most common MS–DRG for patients with surgical AV fistula creations. As such, the applicant does not see a difference in MS–DRG assignment between WavelinQ™ (4F) EndoAVF procedures, other endovascular AVF systems, and traditional surgical AV fistula creation procedures.

With regard to the third criterion, whether the use of the new technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated the WavelinQ™ (4F) EndoAVF System is indicated for the creation of an arteriovenous fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. The applicant further explained that the diagnoses associated with this treatment and the patient population are similar to those treated by existing procedures and technologies that are commercially available, such as surgical AV fistula creation and the Ellipsys® Vascular Access System.

As stated above, the WavelinQ™ (6F) EndoAVF System received FDA approval on June 22, 2018 for use in the ulnar arteries and veins. The WavelinQ™ (4F) EndoAVF System is an expanded access of the WavelinQ™ (6F) EndoAVF System and received FDA clearance on February 6, 2019 for use in the radial arteries and veins as well as the ulnar arteries and veins. In the proposed rule, we stated that it seems that for purposes of use in the ulnar arteries and veins, the WavelinQ™ (4F) EndoAVF System would be considered substantially similar to the WavelinQ™ (6F) EndoAVF System as there are only minor differences (the size of the catheters) between the two devices as explained previously. As a result, we stated that we believe the newness period for the use in the ulnar arteries and veins would begin with the FDA approval of the WavelinQ™ (6F) EndoAVF System (formerly named the everlinQ endoAVF system), which occurred on June 22, 2018, rather than the FDA clearance of the WavelinQ™ (4F) EndoAVF System, which occurred on February 6, 2019. Finally, because the WavelinQ™ (4F) EndoAVF System received FDA clearance on February 6, 2019 for use in the radial arteries and veins, we stated that it seems the newness period for the use of the device in the radial arteries and veins would begin on February 6, 2019.

We also noted that as summarized previously, the applicant provided an explanation for why it believes the WavelinQ™ (4F) EndoAVF System is not substantially similar to the Ellipsys®, specifically with regard to mechanism of action. In the proposed rule we welcomed additional comments on whether the WavelinQ™ (4F) EndoAVF System and the Ellipsys® are substantially similar to each other. We also invited public comments on whether the WavelinQ™ (4F) EndoAVF System is substantially similar to existing technologies and whether it meets the newness criterion.

Comment: The applicant submitted public comments. The applicant stated WavelinQ™ uses an entirely different mechanism of action than any commercially available product or surgical technique.

The applicant also stated that the predicate device, the WavelinQ™ (6F) EndoAVF System received FDA approval on June 22, 2018 for AVFs of the ulnar arteries and ulnar veins. The applicant also agreed that the newness period for the WavelinQ™ 4F EndoAVF System for the radial arteries and radial veins would begin on February 6, 2019.

Another commenter agreed that the creation of endovascular AVFs clearly differs in method of action from surgical AVF creation. However, the commenter stated that while WavelinQ™ and Ellipsys® exhibit differences from each other in their technical characteristics, they do not have fundamentally different mechanisms of action. The commenter further stated that the main differences between the two endovascular systems include the use of two catheters with WavelinQ™ and one with Ellipsys® and the technical characteristics of the catheters, differences in the fistula sites, differences in imaging requirements, and in the source of energy. The commenter added that key similarities include the percutaneous ''side-to-side'' technique, treatment of the same population of patients, and the requirement of additional procedures for blood flow control such as coil embolization with WavelinQ™ and angioplasty with Ellipsys®. They further stated the two technologies could be best described as having a substantially similar mechanism of action and should be considered jointly for purposes of new technology add-on payments eligibility.

Response: We thank the applicant and commenter for their comments. After consideration of the comments received, we agree with the applicant that the WavelinQ™ uses a unique mechanism of action with its dual catheter access of both venous and arterial systems, magnetic linking of the vessels, and additional fistula site, which differs from that of other commercially available devices. Therefore, we believe the WavelinQ™ meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2018 MedPAR database for claims reporting an ICD–10–CM diagnosis code of N18.4, N18.5, or N18.6 to identify cases that may be eligible for the WavelinQ™ (4F) EndoAVF System. The applicant limited their analysis to the following five most common MS–DRGs that the cases mapped to, which accounted for 66 percent of all cases: MS–DRG 252 (Other Vascular Procedures with MCC), 264 (Other Circulatory System O.R. Procedures), 673 (Other Kidney and Urinary Tract Procedures with MCC), 674 (Other Kidney and Urinary Tract Procedures with CC), and 981 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC). This resulted in 2,472 cases across these five MS–DRGs.

The applicant first removed supply charges with a revenue code of 027X and also removed charges for the operating room. Then the applicant standardized the charges. The applicant noted that in order to provide a conservative estimate it did not inflate the charges. The applicant then added charges for the new technology as well as procedure related charges which included operating room charges.

Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $83,372. In the

applicant's analysis, the final inflated average case-weighted standardized charge per case was $121,749. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We invited public comments on whether the WavelinQ™ (4F) EndoAVF System meets the cost criterion.

Comment: The applicant commented that a conservative approach was taken when calculating WavelinQ™ procedure costs. For example, all supply and operating room charges were backed out and inflation was not accounted for in the final calculation. The applicant stated that analysis clearly demonstrates WavelinQ™ (4F) EndoAVF System meets the new technology add-on payments cost criterion.

Response: We appreciate the applicant's comments concerning the cost criterion. After consideration of the public comments we received and based on the cost analysis as described previously, we agree that the WavelinQ™ (4F) EndoAVF System meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the WavelinQ™ (4F) EndoAVF System represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to or ineligible for currently available treatments. The applicant also stated that WavelinQ™ (4F) EndoAVF System represents a substantial clinical improvement over existing technologies because the WavelinQ™ (4F) EndoAVF System significantly improves clinical outcomes for patients requiring hemodialysis in comparison to arteriovenous surgical fistula creation and the Ellipsys® Vascular Access System; offers higher patient satisfaction; provides a beneficial resolution to disease process treatment; and provides additional vascular access options for dialysis.

Surgical arteriovenous fistulae are the recommended type of vascular access for hemodialysis.[354] Despite initiatives to increase AVF use, fistulas are still underutilized with only 17 percent of patients initiating dialysis with an AVF and 67 percent of patients still using a central venous catheter (CVC) at 3 months after dialysis initiation.[355] Failure rates (failure to mature and become usable) for surgical AVF range from 20–60 percent.[356] [357] [358] [359] [360] AVFs also take a long time to mature—approximately 132 days.[361] Furthermore, >83 percent of AVF patients need at least one intervention in the first year,[362] typically receiving 1.5 to 3.3 additional interventions per year to mature and maintain patency.[363] [364] [365] [366] [367]

According to the applicant, in contrast, results of AVFs created using the WavelinQ™ 4F EndoAVF System have shown that endovascular AVFs (endoAVFs) have better results than surgical AVF. The applicant stated that these results include higher patency with fewer post-creation interventions and higher fistula maturation as compared to the surgical AVF results reported in the literature. For example, a recent meta-analysis included four clinical studies with pooled efficacy and safety data from 157 patients using the WavelinQ™ EndoAVF System.[368] According to the applicant, the results include high procedure success of 96.8 percent and higher cannulation success than surgical AVF—82.4 percent of patients were successfully used for dialysis by 6 months. Also, the applicant asserted that the results include higher patency than surgical AVF, demonstrated by 74.8 percent primary patency (unobstruction without additional intervention) at 12 months, 79.0 percent secondary patency (unobstruction) at 12 months, and 98.12 percent functional patency (durability post-cannulation) at 12 months. The FLEX study was a prospective, single arm safety and feasibility study (using the WavelinQ™ (6F) EndoAVF System) that reported a procedure success rate of 97 percent and that 96 percent of endoAVFs were used for dialysis and remained patent after 6 months.[369]

The applicant indicated that a second study, the Novel Endovascular Access Trial (NEAT), which was a statistically powered, prospective, single-arm, multi-center study of 60 evaluable patients and 20 roll-ins using the WavelinQ™ (6F) EndoAVF System, confirmed previous results with high procedure and cannulation success of 98 percent and 67 percent (within 12 months), respectively. Additionally, the study demonstrated a low thrombosis rate of 10.5 percent, low intervention rate of 0.46 per patient-year, and high 12-month primary and secondary patency of 69 percent and 84 percent, respectively.[370]

The applicant stated that additional analyses comparing endoAVF (using the WavelinQ™ (6F) EndoAVF System) to surgical AVF showed that patients with an endoAVF had fewer secondary interventions in the first year as compared to patients with a surgical AVF, resulting in overall cost savings to payers. According to the applicant, 67 percent of endoAVF patients were free from intervention after 1 year compared to only 18 percent of surgical AVF patients.[371] [372]

The applicant also included a third study, the EASE study, which was a single-center, single-arm prospective study of 32 patients that evaluated the

[354] National Kidney Foundation Disease Outcomes Quality Initiative (NKF–KDOQI). ''KDOQI Clinical practice guideline for vascular access, *American Journal of Kidney Diseases,* 2006, 48 (suppl 1), S176–S276.

[355] USRDS Annual Report, 2017.

[356] Asif, et al., ''Early arteriovenous fistula failure: A logical proposal for when and how to intervene,'' *Clinical Journal of American Society of Nephrology,* 2006, 1: pp. 332–339.

[357] Dember, et al., ''Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: A randomized controlled trial,'' *JAMA,* 2008, 299, pp. 2164–2171.

[358] Al-Jaishi, et al., ''Patency rates of the arteriovenous fistula for hemodialysis: A systematic review and meta-analysis,'' *American Journal of Kidney Diseases,* 2014, 63, pp. 464–478.

[359] USRDS Annual Report, 2017.

[360] Thamer, et al., ''Medicare costs associated with arteriovenous fistulas,'' *American Journal of Kidney Diseases,* 72(1), pp. 10–8. Published online March 28, 2018.

[361] USRDS Annual Report, 2017.

[362] Thamer, et al., ''Medicare costs associated with arteriovenous fistulas,'' *American Journal of Kidney Diseases,* 72(1), pp. 10–18. Published online March 28, 2018.

[363] Lee, et al., ''Tradeoffs in vascular access selection in elderly patients initiating hemodialysis with a catheter,'' *American Journal of Kidney Diseases,* 2018.

[364] Yang, et al., ''Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation,'' *The Journal of Vascular Access,* 2017, 18, pp. 8–14.

[365] Arnold, et al., ''Evaluation of hemodialysis arteriovenous fistula interventions and associated costs: Comparison between surgical and endovascular AV fistula,'' *Journal of Vascular and Interventional Radiology* 2018, pp. 1–9.

[366] Buickians, et al., ''The natural history of autologous fistulas as first-time dialysis access in the KDOQI era,'' *Journal of Vascular Surgery,*'' 2008, 47, pp. 415–421, discussion 20–1.

[367] Falk, et al., ''Maintenance and salvage of arteriovenous fistulas,'' *Journal of Vascular Interventional Radiology,* 2006, 17, pp. 807–813.

[368] BD WavelinQ Instructions for Use, BAW1469200 Rev. 0 02/19.

[369] Rajan, et al., ''Percutaneous creation of an arteriovenous fistula for hemodialysis access,'' *Journal of Vascular Intervenous Radiol*ogy, 2015, 26, pp. 484–490.

[370] Lok, et al., ''Endovascular proximal forearm arteriovenous fistula for hemodialysis access: Results of the prospective, multicenter novel endovascular access trial (NEAT),'' *American Journal of Kidney Diseases,* 2017, 70, pp. 486–497.

[371] Yang, et al., ''Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation,'' *The Journal of Vascular Access,* 2017, 18, pp. 8–14.

[372] Arnold, et al., ''Evaluation of hemodialysis arteriovenous fistula interventions and associated costs: Comparison between surgical and endovascular AV fistula,'' *Journal of Vascular Intervenous Radiol*ogy, 2018, pp. 1–9.

safety and efficacy of the WavelinQ™ (4F) EndoAVF System. The applicant stated that results from EASE were consistent with previous studies, demonstrating 100 percent procedure success with a low adverse event rate, 1/32 (3.1 percent). The lower adverse event rate was attributed to arterial access from the wrist, which was utilized in 79 percent of patients. We note that arterial wrist access is not approved in the U.S. 6-month primary patency was 83 percent. At 6 months, 86 percent of patients were successfully cannulated for dialysis using the WavelinQ™ (4F) EndoAVF System.[373]

Additionally, the applicant noted that a fourth study, the EndoAVF EU Study (using the WavelinQ™ (4F) EndoAVF System), is still enrolling. Outcomes for the first 32 patients were tabulated and included in the meta-analysis and showed consistent results to previous studies.[374]

The applicant asserted the FLEX, NEAT, EASE, and EndoAVF EU Study support that the WavelinQ™ (4F) EndoAVF System results in much lower maintenance and morbidity than the traditional surgical AVF in end-stage renal failure patients, with intervention rates for endoAVF ranging from 0.21–0.6 per patient-year and fistula maturation rates up to 86 percent at 6 months.[375] [376] [377]

The applicant also asserted the reduction in interventions with the WavelinQ™ (4F) EndoAVF System is a result of the unique procedure that minimizes vessel trauma. According to the applicant, the system creates a fistula by using radiofrequency to vaporize tissue between the artery and concomitant vein with minimal vessel trauma or manipulation of the vessels, potentially lessening the stimulus for negative remodeling that leads to frequent interventions.

The applicant stated the WavelinQ™ (4F) EndoAVF System offers higher patient satisfaction and beneficial resolution to disease process treatment compared to surgical AVF. According to the applicant, the team Lok, C et al. was interested in patient acceptance of an endoAVF (based on the WavelinQ™ (6F) EndoAVF System) because up to 30 percent of patients refuse a surgically created AV fistula according to the reported literature.[378] [379] Therefore, the team collected data on patient satisfaction using a validated patient questionnaire to learn more about the patient experience with this new technology using responses from patients in the NEAT trial. The applicant asserted that results indicate patients are very satisfied with their endoAVF and would not change to another type of access.

The applicant explained some of the clinical and patient benefits of the WavelinQ™ (4F) EndoAVF System. The applicant asserts, for example, that endoAVF allows the patient to avoid open surgery, scarring, and arm disfigurement, which is important to many patients. The applicant further asserted that the endoAVF procedure improves the process of administering hemodialysis as the endoAVF matures faster compared to a surgical AVF, allowing the patient to more quickly transition away from a central venous catheter, which the applicant stated has a high rate of complication including infection. In addition, the applicant stated that WavelinQ™ (4F) EndoAVF requires less follow-on maintenance such that patients are not in and out of the hospital for additional interventions to maintain the primary patency of the fistula.[380] [381] The applicant stated that this has the potential to increase patient acceptance of an AVF as surgical fatigue is cited as the primary reason patients elect a permanent CVC over a surgical AVF.[382] The applicant also suggested the WavelinQ™ (4F) EndoAVF System provides additional vascular access options for dialysis in comparison to surgical AVF and the Ellipsys® Vascular Access System.[383] [384]

The applicant asserted the WavelinQ™ (4F) EndoAVF System creates additional options for establishing arteriovenous access, that is another anatomic site for creating a fistula that neither traditional surgical AVFs nor the Ellipsys® Vascular Access System can offer. According to the applicant, patients are given an extra location in the mid-arm for a fistula because the WavelinQ™ (4F) EndoAVF System uses vessels deep in the arm that are not used in surgical fistula creation and are only accessible endovascularly via the unique mechanism of WavelinQ™ consisting of action using magnetically-guided arterial and venous catheters. The applicant suggested this additional access creation site extends the potential time a patient can undergo dialysis with an autogenous fistula before exhausting vessels and requiring an AV graft or CVC.

The applicant asserted the WavelinQ™ (4F) EndoAVF System is indicated for the creation of an arteriovenous fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. According to the applicant, the ulnar artery to ulnar vein fistula is unique to the WavelinQ™ (4F) EndoAVF System in comparison to both traditional surgical fistula creation and the Ellipsys® Vascular Access System. The applicant stated that it enables the preservation of all future surgical AVF options such as a radiocephalic, brachiocephalic and brachiobasilic fistula as it utilizes an entirely different vascular bed for both arterial and venous blood flow.

With regard to the information previously summarized, we stated in the proposed rule that we are concerned that there is no study directly comparing WavelinQ™ (4F) EndoAVF System to surgical AVF or Ellipsys® Vascular Access System; rather, the studies provided compare historical data for surgical AVF to data on the results of AVF created using both the WavelinQ™ EndoAVF (6F) and (4F) systems. We stated that we are also concerned as to whether the data demonstrates if the WavelinQ™ (4F) EndoAVF System significantly improves clinical outcomes for patients requiring

[373] Berland, et al., Endovascular Creation of an Arteriovenous Fistula with a Next Generation 4Fr Device Design for Hemodialysis Access: Clinical Experience from the EASE Study.

[374] Rajan, et al., ''Percutaneous creation of an arteriovenous fistula for hemodialysis access,'' *Journal of Vascular Intervenous Radiol*ogy, 2015, 26, pp. 484–490.

[375] Lee, et al., ''Tradeoffs in vascular access selection in elderly patients initiating hemodialysis with a catheter,'' *American Journal of Kidney Diseases,* 2018.

[376] Harms, et al., ''Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use,'' *Journal of Vascular Surgery,*'' 2016, 64(1), pp. 155–162.

[377] Berland et al., Endovascular Creation of an Arteriovenous Fistula with a Next Generation 4Fr Device Design for Hemodialysis Access: Clinical Experience from the EASE Study.

[378] Lok, C. et al., ''Patient perceptions of a new non-surgical approach to arteriovenous fistula creation and use for hemodialysis,'' *Nephrology Dialysis Transplantation,* 2017, 32 (Supplement 3) iii329–iii343.

[379] Casey, et al., ''Patients' perspectives on hemodialysis vascular access: A systematic review of qualitative studies,'' *American Journal of Kidney Diseases,* 2014, vol. 64, pp. 937–953.

[380] Yang, et al., ''Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation,'' *The Journal of Vascular Access,* 2017, 18, pp. 8–14.

[381] Arnold, et al., ''Evaluation of hemodialysis arteriovenous fistula interventions and associated costs: Comparison between surgical and endovascular AV fistula,'' *Journal of Vascular Intervenous Radiology,* 2018, pp. 1–9.

[382] Chaudhry, et al., ''Seeing eye to eye: The key to reducing catheter use,'' *The Journal of Vascular Access,* 2011, 12, pp. 120–126.

[383] BD WavelinQ Instructions for Use, BAW1469200 Rev. 0 02/19.

[384] Avenue Medical Ellypsis Instructions for Use, LB015–002 Rev B, Released 11/2018.

hemodialysis in comparison to surgical AVF and the Ellipsys® Vascular Access System due to the limited number of participants in the clinical trials, and whether the results are generalizable to the entire Medicare population due to the limited number of participants.

We invited public comments on whether the WavelinQ™ (4F) EndoAVF System meets the substantial clinical improvement criterion.

Comment: The applicant submitted public comments regarding CMS' concerns. The applicant asserted that the peer-reviewed, published data from controlled clinical studies demonstrates that the WavelinQ™ (4F) EndoAVF system offers multiple clinical advantages over surgical AVFs for patients in end-stage renal disease who require hemodialysis via an arteriovenous fistula.[385]

The applicant also addressed a question regarding available randomized, controlled studies comparing the WavelinQ™ (4F) EndoAVF System to surgical AVFs. The applicant asserted, that as stated during the Town Hall, while there are no current head-to-head RCTs comparing the two fistula types, there are two published retrospective studies that utilize a Propensity Score Matching Analysis to compare WavelinQ™ data from the NEAT study with two separate data sources for AVF patients.

The applicant stated that the first study was conducted by Yang et al. and was published in the *Journal of Vascular Access* in 2017. This study compared AVF post-creation procedures and their associated costs for patients with surgical AV fistulas to patients with fistulas created using WavelinQ™. A random 5 percent sample from Medicare's Standard Analytic Files was extracted and used in comparison to patients from the NEAT study. Patients were matched 1:1 using propensity score matching of baseline demographic and clinical characteristics. Patient follow up data from inpatient, outpatient, and physician claims were used to identify post-creation procedures and to estimate average procedure costs. Of 3,764 Medicare surgical AVF patients, 60 successfully matched 1:1 with patients from the NEAT study. Key results were as follows:

- Post-creation procedural event rate was 3.43 per patient year and 0.59 per patient-year ($p<0.05$) for surgical and WavelinQ™ fistulas, respectively.
- Average first year post-AVF creation costs per patient-year for patients who received a WavelinQ™ fistula were $11,240 USD lower than costs for a surgical fistula.

The second study was conducted by Arnold et al. and was published in the *Journal of Vascular Interventional Radiology* in 2018. This study compared the rate of AVF interventions in both incident and prevalent end-stage kidney disease patients, their associated costs, and intervention-free survival between patients with surgically created AVFs vs. patients with an endoAVF created using WavelinQ™. Data from the USRDS was abstracted and matched 1:1 with patients from the NEAT study using propensity score matching. Post fistula creation event rates, intervention-free survival, and costs were compared between patients with surgically created fistulas and patients with a WavelinQ™ fistula. The applicant stated that key results were as follows:

- In incident patients, post-creation event rates were 7.22 per patient-year and 0.74 per patient-year ($p<0.0001$) for surgical and WavelinQ™ fistulas, respectively.
- In prevalent patients, post-creation event rates were 4.10 per patient-year and 0.46 per patient-year ($p<0.0001$) for surgical and WavelinQ™ fistulas, respectively.
- Expenditures for post-creation interventions were $16,494 and $13,389 less in incident and prevalent patients with a WavelinQ™ fistula, respectively.

The applicant also provided written comments addressing the availability of data from the EU Post-Market Study. The applicant stated that while there are no plans at this time to publish the EU Post-Market Study in a medical journal, the data have been made available to the public via WavelinQ™'s Instructions for Use (IFU). The applicant also provided a PDF copy of the most recent IFU which contained a summary of the study safety and effectiveness measures.

The applicant also explained the peer-reviewed, published data from controlled clinical studies. The applicant stated that the studies demonstrate that the WavelinQ™ 4F EndoAVF System offers multiple clinical advantages over surgical AVFs for patients suffering from end-stage renal disease who require hemodialysis via an arteriovenous fistula.[386]

The applicant included a *JVA* 2020 publication to address concerns raised by CMS in the proposed rule that there is no study directly comparing WavelinQ™ 4F EndoAVF System to surgical AVF. The applicant provided the recent Inston et al. publication,[387] which outlines a single center study that compared 30 WavelinQ™ 4F EndoAVF procedures with a matched cohort of 40 surgical AVFs. The applicant further pointed out that prospective data was collected on both cohorts from 2016–2019 and analyzed to evaluate outcomes. The applicant provided the following highlights from the publication:

- Outcomes from Inston et al. demonstrated that the WavelinQ™ group provided better results as compared to the surgical radiocephalic AVF (sAVF) group in every major clinical category:
  - Procedural success rate, time to cannulation, primary and secondary patency
  - These metrics were used to evaluate efficacy in the other major WavelinQ™ publications such as EASE, EASE–2, FLEX, NEAT and the EU Post-Market Study [388]
- Procedural success was 96.7% in WavelinQ™ group, and 92.6% in sAVF group
- Mean time to cannulation was 130 days (±86) in the WavelinQ™ group, and 141 days (±118) in the sAVF group
- Primary patency at 6 and 12 months:
  - WavelinQ™ group was 65.5% and 56.5% respectively
  - sAVF group was 53.4% and 44%, respectively ($p = 0.69$ and 0.63)
- Mean primary patency was significantly better for the WavelinQ™ group (362 ± 240 days) vs. the sAVF group (235 ± 210 days) ($p <0.05$)
- Secondary patency at 6 and 12 months:
  - WavelinQ™ group at 6 and 12 months was 75.8% and 69.5%, respectively
  - sAVF group was lower at 66.7% and 57.6% at 6 and 12 months, respectively
- The ages in both groups in the study were also generally consistent with other published literature: 57 ± 15 in the WavelinQ™ group, and 54 ± 17 in the sAVF group.

The applicant stated that patients that received the WavelinQ™ EndoAVF demonstrated superior outcomes when compared to a contemporaneous group

[385] Berland Presentation NTAP Town Hall on December 16, 2019.

[386] During the NTAP Town Hall on December 16, 2019, Dr. Todd Berland from NYU Langone Medical Center presented evidence that clearly showed WavelinQ provided a substantial clinical improvement over surgical AVF creation. See You Tube video on *CMS.gov.*

[387] Inston, N., et al. WavelinQ created arteriovenous fistulas v, surgical radiocephalic arteriovenous fistulas? A single-centre observational study. *The Journal of Vascular Access.* 2020 Jan;21(1):7–18 *https://doi.org/10.1177/1129729819897168.*

[388] WavelinQ™ EndoAVF System Instructions for Use, BAW1469200 Rev. 0 02/19.

of patients that received surgical AVFs. The applicant asserted these data not only support that the WavelinQ™ 4F EndoAVF System is effective, but that it may be considered as a first treatment option over surgical AVF, particularly if vessels at the wrist are absent or less than ideal. The applicant stated that it is important to note that the Inston et al., published clinical data on WavelinQ™ are similar to other results in published literature.[389]

The applicant asserted that Inston et al. also provides an alternative to retrospective propensity-matched analyses (Yang and Arnold, et al.), and is a new, positive contribution to the overall body of evidence in that it is more reflective of the real-world setting. The applicant claimed these data further support the efficacy of endoAVF with WavelinQ™ and demonstrate substantial clinical improvement of endoAVF with WavelinQ™ over surgical AVFs.

The applicant claimed that in addition to demonstrating significant improvements in efficacy vs. a surgically created fistula, WavelinQ™ endoAVFs provide a significant improvement in patients' quality of life. The study by Lok et al. evaluated end-stage renal disease (ESRD) patients with a WavelinQ™ EndoAVF for dialysis to determine patient satisfaction with vascular access-related issues that impact quality of life at baseline, 6 months and 12 months post-procedure. The applicant asserted the study results showed that 96 percent of patients were satisfied with the WavelinQ™ EndoAVF, 72 percent would recommend the WavelinQ™ EndoAVF to a friend, 88 percent found it easy to use, and only 16 percent would change their AVF access type if possible.[390]

The applicant also provided a clinical comparison of the WavelinQ™ 4F EndoAVF System to the Ellipsys® Vascular Access System. The applicant stated that CMS noted the lack of a study directly comparing WavelinQ™ to Ellipsys®. The applicant explained there are several reasons why a head-to-head study was not conducted. According to the applicant, the first reason is the WavelinQ™ 6F EndoAVF System, and the Ellipsys® Vascular Access System were both approved by FDA on June 22, 2018. According to the applicant, the FDA would not allow a study comparing two unapproved technologies to each other. The second reason, according to the applicant, is both WavelinQ™ and Ellipsys® were studied/compared to surgical AVFs, the current standard of care, which is generally the recommended approach. Given the timeline for planning, enrolling, and completing a study and then having a journal article published, it would have been logistically impossible to conduct and publish a robust, multi-center head-to-head study (*WavelinQ*™ vs. *Ellipsys*®) in the short period of time from FDA approval of the two devices to date. The applicant further explained any such study results would likely be available only after expiration of WavelinQ™'s new technology add-on payment newness eligibility.

The applicant further stated that the clinical, technological, and procedural differences between WavelinQ™ and Ellipsys® would contribute to the complexity of structuring a head-to-head study. The applicant claimed any direct comparison would need to account for the subsequent procedure(s) that are needed when the Ellipsys® system is used. Ellipsys® typically requires balloon angioplasty to assist with maturation. The applicant stated that additionally, the limited access points and visualization options of Ellipsys® are different from WavelinQ™. The applicant stated these differences would make it extremely challenging to find physicians with adequate ultrasound skills, and because Ellipsys® allows only one site for a creation of an AVF, patient enrollment would have been very difficult. Thus, the applicant stated the differences in both products, product indications, and the procedures would provide significant hurdles to designing and completing such a study.

The applicant also commented in response to CMS's concern regarding whether the composition of clinical trial enrollees is generalizable to the Medicare population. The applicant asserted that an analysis of the 2018 USRDS data shows that patients enrolled in the WavelinQ™ clinical trials are representative of the Medicare population, based on the average age in the studies. Additionally, the applicant asserted ESRD patients commonly access the Medicare program outside of traditional age-based enrollment.

The applicant noted that according to the 2018 USRDS report, 47.9 percent of all incident hemodialysis patients are under the age of 65 (52,201/108,895) and that 52.6 percent of all prevalent hemodialysis patients are also under the age of 65 (241,037/457,957).[391]

The applicant asserted that before WavelinQ™ was cleared by the FDA, industry discussed the WavelinQ™ procedure and initial data with CMS medical officers and the Coverage and Analysis Group. The applicant stated CMS medical officers indicated current Medicare ESRD patients had more comorbidities as compared to ESRD populations studied 20 years ago. CMS' recommendations from this meeting were to (1) compare WavelinQ™ study data to the current data available in the USRDS database to determine if WavelinQ™ study populations were representative of the current Medicare population, and (2) compare the number of re-interventions with surgical and WavelinQ™ endoAVFs.[392] As a result of these discussions, the applicant compared a contemporaneous patient cohort to USRDS data to demonstrate that the WavelinQ™ endoAVF patient population was representative of Medicare population.[393] The applicant stated that while fewer African-American patients were enrolled in the early study, later studies included more diverse patient populations including more patients who are Hispanic and Asian.

The applicant stated the Arnold et al. analysis also demonstrated that WavelinQ™ patients had fewer subsequent re-interventions and therefore created cost-savings for Medicare.[394] The applicant stated that the published results from this analysis comparing surgical and endoAVFs clearly demonstrate that the existing published study results from WavelinQ™ are generalizable to the Medicare population in that these patients have ESRD and require dialysis.

The applicant also stated that a propensity score matched analysis was conducted by Yang et al. that compared

[389] Inston, N., et al. WavelinQ created arteriovenous fistulas v, surgical radiocephalic arteriovenous fistulas? A single-centre observational study. The Journal of Vascular Access. 2020 Jan;21(1):7–18 *https://doi.org/10.1177/1129729819897168.*

[390] Lok, C. et al., Patient Perceptions of a New Non-Surgical Approach to Arteriovenous Fistula Creation and Use for Hemodialysis. Nephrology Dialysis Transplantation 32 (Supplement 3): iii329–iii343, 2017.

[391] *https://www.usrds.org/2018/view/v2_01.aspx*, Data Table T1.6 incident ESRD patients and Table T1.7 prevalent ESRD patients.

[392] Arnold, R.J., Han, Y., Balakrishnan, R., Layton, A., Lok, C.E., Glickman, M., Rajan, D.K. Comparison between Surgical and Endovascular Hemodialysis Arteriovenous Fistula Interventions and Associated Costs. Journal of Vascular and Interventional Radiology. 2018 Oct; 29(11), 1558–1566. doi:10.1016/j.jvir.2018.05.014.

[393] Inston, N., et al. WavelinQ created arteriovenous fistulas v, surgical radiocephalic arteriovenous fistulas? A single-centre observational study. The Journal of Vascular Access. 2020 Jan;21(1):7–18 *https://doi.org/10.1177/1129729819897168.*

[394] Arnold, R.J., Han, Y., Balakrishnan, R., Layton, A., Lok, C.E., Glickman, M., Rajan, D.K. Comparison between Surgical and Endovascular Hemodialysis Arteriovenous Fistula Interventions and Associated Costs. Journal of Vascular and Interventional Radiology. 2018 Oct; 29(11), 1558–1566. doi:10.1016/j.jvir.2018.05.014.

patients with a WavelinQ™ endoAVF fistula from the Novel Endovascular Access Trial (NEAT) with a 5 percent random sample of patients with surgically created AVFs from the Medicare Standard Analytic files.[395] The applicant further stated post-fistula creation procedures and their associated costs were analyzed. The applicant added that of the 3,764 Medicare surgical AVF (sAVF) patients, 60 successfully matched to the endoAVF patients from the NEAT study using 1:1 propensity score matching of baseline demographic and clinical characteristics. The applicant concluded that after propensity score-matching, there were no statistical differences baseline demographic or clinical characteristics between groups.

Total cost (in 2014 US$)	$1,794	$13,033	

The applicant asserted the study by Yang et al.[396] demonstrated that a WavelinQ™ EndoAVF outperformed a surgical AVF in a propensity score-matched U.S. population with similar baseline demographics and clinical characteristics. The applicant also asserted that the WavelinQ™ EndoAVF demonstrated a monetary savings for the health system due to a reduced post-AVF creation procedure event rate.

The applicant also stated that Arnold et al.[397] conducted a second propensity score matched analysis comparing the patients from the NEAT study to a sample of patients from the USRDS database. Patients were matched 1:1 according to baseline demographics and clinical characteristics. Both incident and prevalent patients were evaluated separately. Results for both groups were as follows:

Incident Patients

	WavelinQ™ EndoAVF	sAVF	Difference
Total event rate per patient-year	0.744	7.216	6.472
Total cost ($US)	$814.60	$17,443.10	$16,494.50

The applicant stated in the incident patient population, WavelinQ™ EndoAVF demonstrated 6.472 fewer events per patient-year compared to a surgically created fistula. Correspondingly, the total cost difference to treat these patients was $16,494.50 less expensive in the WavelinQ™ EndoAVF group.

Prevalent Patients

	WavelinQ™ EndoAVF	sAVF	Difference
Total event rate per patient-year	0.459	4.098	3.639
Total cost ($US)	$1,134.24	$14,523.15	$13,388.92

The applicant further stated that in the prevalent patient population, WavelinQ™ EndoAVF demonstrated 3.639 fewer events per patient-year compared to a surgically created fistula. Correspondingly, the total cost difference to treat these patients was $13,388.92 less expensive in the WavelinQ™ EndoAVF group.

The applicant also stated that a voluntary recall of WavelinQ™ 4F was initiated in April 2019 that was specific to one lot (150 units) of catheters. Of these, 136 units were never sold or were successfully returned to BD prior to use. Of the 14 remaining catheters that were not returned to BD, there have been no reported patient injuries. This lot of catheters was found to have magnets that did not meet BD's requirements for magnetic strength. The magnets are used to pull the arterial and venous vessels into close approximation to create the endovascular fistula using RF energy. Without the necessary coaptation of the magnets, endoAVF cannot be performed. BD was able to identify the root cause of the weak magnets and implemented corrective actions that were completed in June 2019 and submitted to the FDA. The applicant stated that they have not received any additional complaints of a similar nature.

We also received another public comment regarding whether WavelinQ™ provides a substantial clinical improvement over existing technologies. The commenter asserted that Ellipsys® is not clinically inferior to WavelinQ™, and in fact the evidence available shows that the Ellipsys® has a

[395] Yang, S., Lok, C., et al. Comparison of Post-Creation Procedures and Costs between Surgical and an Endovascular Approach to AVF Creation. The Journal of Vascular Access. 2017 Mar; 18(Supplement 2), S8–S14. doi:10.5301/jva.5000723.

[396] Yang, S., Lok, C., et al. Comparison of Post-Creation Procedures and Costs between Surgical and an Endovascular Approach to AVF Creation. The Journal of Vascular Access. 2017 Mar; 18(Supplement 2), S8–S14. doi:10.5301/jva.5000723.

[397] Arnold, R.J., Han, Y., Balakrishnan, R., Layton, A., Lok, C.E., Glickman, M., Rajan, D.K. Comparison between Surgical and Endovascular Hemodialysis Arteriovenous Fistula Interventions and Associated Costs. Journal of Vascular and Interventional Radiology. 2018 Oct; 29(11), 1558–1566. doi:10.1016/j.jvir.2018.05.014.

better record of a number of key outcomes, including technical success and cumulative patency. The commenter cited a recently published abstract [398] which reported on a retrospective review of a single-center, single-operator case series of 100 pAVFs created from December 2017 to July 2019, 65 with Ellipsys® and 35 with WavelinQ™. The study reported technical success with Ellipsys® was 100 percent vs. 97 percent with WavelinQ™. Maturation at four weeks was 68.3 percent vs. 54.3 percent; median time to cannulation was 60 vs. 90 days. Successful dialysis access was achieved in 79.5 percent of Ellipsys® cases vs. 58 percent for WavelinQ™ cases. Interventions were performed in approximately 27 percent of cases for both technologies, and the number of interventions per patient-year was 0.96 vs. 0.46. At 12 months, secondary patency was significantly higher for Ellipsys® patients (82 percent) vs. WavelinQ™ patients (60 percent), according to the study.

The commenter stated that percutaneous AVF technology represents a significant clinical improvement relative to surgical AVFs, for patients for which this approach is anatomically suitable. The commenter asserted that WavelinQ™ has not demonstrated a significant clinical improvement relative to Ellipsys®.

Response: After consideration of the comments we received and upon further review, we continue to have concerns with respect to whether WavelinQ™ meets the substantial clinical improvement criterion for new technology add-on payments. In our proposed rule, we stated that we were concerned there is no study directly comparing the WavelinQ™ 4F EndoAVF System to surgical AVF or the Ellipsys® Vascular Access System; rather, the studies provided compare historical data for surgical AVF to data on the results of AVF created using both the WavelinQ™ EndoAVF (6F) and (4F) systems. The applicant cited a recent study by Inston et al.[399] which outlines a single-center study that compared 30 WavelinQ™ 4F EndoAVF procedures with a matched cohort of 40 surgical AVFs. The study reported that the mean primary patency was significantly better for the WavelinQ™ group (362 ± 240 days) vs. the sAVF group (235 ± 210 days) ($p < 0.05$) which was a statistically significant difference. However, all other parameters reported in the study did not demonstrate statistically significant differences, including procedural success rate, time to cannulation, 6 and 12 month primary patency, and secondary patency with WavelinQ™. In addition, the number of interventions per patient year were higher in the WavelinQ™ arm than in the sAVF arm (0.402 vs 0.273). Another study comparing the use of WavelinQ™ and Ellipsys® showed Ellipsys outperformed WavelinQ at multiple endpoints, with 12 month secondary patency significantly higher for Ellipsys® (82 percent vs 60 percent).

We appreciate the comments and additional information regarding whether the WavelinQ™ represents a significant clinical improvement.

In addition to the comments we received, CMS also reviewed a published study on the real-world usage of the WavelinQ™ EndoAVF System.[400] This study examined a single center's success rates and short-term follow-up using the WavelinQ™ EndoAVF. Study subjects included patients who underwent placement of a fistula using the WavelinQ™ EndoAVF system from October 2018 to July 2019. Preoperative/intraoperative variables including demographics, preoperative/postoperative duplex ultrasonography, success rate of procedure, and subsequent endovascular/surgical procedures were obtained. Descriptive statistics and comparison of groups requiring subsequent intervention were performed.

Thirty-five patients underwent placement of the WavelinQ™ AVF, with 32 patients (91 percent) having at least one documented follow-up. These patients were predominantly male (23/32, 72 percent) with an average age of 60.2 and 23 of 32 patients (72 percent) were on dialysis. Initial fistula creation success rate was 100 percent. Average procedural length was 120 minutes, fluoroscopy time 9.6 minutes, and contrast usage 52.2 mL. Eight of 32 patients (25 percent) had perioperative complications (3 hematomas, 3 contrast extravasations, 1 resolved vessel spasm all resolving spontaneously, and 1 pseudoaneurysm requiring surgical repair). Thirteen of 32 patients (41 percent) underwent subsequent endovascular interventions to assist with maturation [9/32 (28 percent) branch coiling, 5/32 (16 percent) angioplasty/stenting, and 3/32 (9 percent) access thrombectomy] and 4 of 32 patients (13 percent) required subsequent surgical interventions (1 pseudoaneurysm repair, 1 revision of fistula, and 2 definitive AVF creation in thrombosed grafts). The majority of accesses (30/32, 94 percent) were ulnar–ulnar fistulas and overall patency at average follow-up of 73 days was 88 percent (28/32) with average brachial artery inflow volume of 1,078 cc/min and average cephalic vein (18/32) outflow volume of 447 cc/min. Eleven of 23 patients (48 percent) on dialysis were successfully using the endoAVF at follow-up.

The study concluded that the WavelinQ™ EndoAVF System has a high initial procedural success rate (100 percent), although a significant portion of patients require subsequent endovascular procedures to aid in maturation. According to the study's conclusion, further work is needed on determining factors predictive of the need for re-intervention for patients with fistulas created using the WavelinQ™ EndoAVF System. In follow-up, 15 of 32 patients (47 percent) underwent surgical and/or endovascular procedures, with 4 of 32 patients (13 percent) requiring subsequent surgical interventions. This included 1 pseudoaneurysm repair, 1 revision of fistula, and 2 definitive AVF creation in thrombosed grafts. In 13 of 32 patients (41 percent), an endovascular procedure was performed subsequent to the fistula placement, most of which were needed to aid in fistula maturation. This included 3 of 32 (9 percent) graft thrombectomies (2 ultimately unsuccessful requiring definitive AVF creation), 5 of 32 (16 percent) angioplasties/stenting of outflow veins, and 9 of 32 (28 percent) vein branch coiling.

After consideration of the public comments we received and based on the information stated above, we believe additional data is needed to demonstrate that WavelinQ™ represents a substantial clinical improvement over existing therapies. Therefore, we are not approving new technology add-on payments for the WavelinQ™ 4F EndoAVF System for FY 2021.

[398] Shahverdyan R, *et al.,* ''Comparison of Outcomes of Percutaneous Arteriovenous Fistulae Creation by Ellipsys and WavelinQ Devices,'' *Journal of Vascular and Interventional Radiology;* accepted for publication: In press. See also an earlier abstract reporting on a preliminary stage of this study: Shahverdyan R, *et al.,* ''Single-Center Experience of Endovascular Arteriovenous Fistula Creation with Both WavelinQ and Ellipsys Systems,'' *Journal of Vascular Surgery* 2019; 70: e173–e174. (November Supplement 2019.)

[399] Inston, N., et al. WavelinQ created arteriovenous fistulas v, surgical radiocephalic arteriovenous fistulas? A single-centre observational study. The Journal of Vascular Access. 2020 Jan;21(1):7–18 *https://doi.org/10.1177/1129729819897168.*

[400] Zemela MS, Minami HR, Alvarez AC, Smeds MR. Real-World Usage of the WavelinQ EndoAVF System [published online ahead of print, 2020 May 15]. Ann Vasc Surg. 2020;S0890–5096(20)30376–9. doi:10.1016/j.avsg.2020.05.006.

l. Zulresso™

Sage Therapeutics submitted an application for new technology add-on payments for ZULRESSO™ for FY 2021. ZULRESSO™ (brexanolone) is a neuroactive steroid gamma-aminobutyric acid $(GABA)_A$ receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults that is administered via a continuous intravenous infusion.

According to the applicant, PPD is a major depressive episode that occurs following delivery, though onset of symptoms may occur during pregnancy. Per the applicant, mothers with PPD may present with a variety of symptoms, which must be present most of the time for 2 weeks or more in order for PPD to be diagnosed. These depressive symptoms may persist throughout and beyond the first postnatal year if PPD is left untreated. As described by the applicant, these symptoms may include trouble bonding with, and doubt in ability to care for, their baby; thoughts of self-harm or harm to the baby; feelings of worry, anxiety, sadness, moodiness, irritability, and/or restlessness; crying more often or without apparent reason; experiencing anger or rage; sleep disturbances; changes in appetite; difficulty concentrating; and withdrawal from friends and family. According to the applicant, PPD may affect the mother's ability to function with potential considerable risks such as self-harm, and PPD may also be associated with suicidal ideation.

The applicant stated that PPD is one of the most common complications during and after pregnancy, affecting more than 400,000 women in the United States. The applicant noted that women diagnosed with PPD who are disabled may be otherwise eligible for Medicare, and some may be eligible for Medicaid as well. While the studies summarized did not specifically target Medicare patients, the applicant believes that these results can be generalized to Medicare patients diagnosed with PPD.

The applicant stated that the precise cause of PPD is unknown, though there are multiple hypotheses about the mechanism of disease of PPD. The applicant reported that levels of allopregnanolone, the predominant metabolite of progesterone, increase during pregnancy and decrease substantially after childbirth. Per the applicant, preclinical evidence indicated that rapid changes in levels of allopregnanolone confer dramatic behavioral changes and may trigger PPD in some women.[401]

As reported in a study submitted by the applicant, the GABAergic deficit hypothesis of depression states that a deficit of GABAergic transmission in defined neural circuits is causal for depression. According to the study, conversely, an enhancement of GABA transmission, including that triggered by selective serotonin reuptake inhibitors or ketamine, has antidepressant effects. The study reported that ZULRESSO™, an intravenous formulation of the endogenous neurosteroid allopregnanolone, showed clinically significant antidepressant activity in postpartum depression. According to the study, by allosterically enhancing $GABA_A$ receptor function, the antidepressant activity of allopregnanolone is attributed to an increase in GABAergic inhibition. In addition, allopregnanolone may stabilize normal mood by decreasing the activity of stress-responsive dentate granule cells and thereby sustain resilience behavior. The researchers concluded that therefore, allopregnanolone may augment and extend its antidepressant activity by fostering resilience.[402]

The applicant stated that prior to FDA approval of ZULRESSO™, there were no medications specifically indicated for PPD. The applicant indicated that the regimens historically employed for the treatment of patients who have been diagnosed with PPD have generally consisted of medications typically used for major depression or other mood disorders. As described by the applicant, these pharmacological therapies include—

- Selective serotonin reuptake inhibitors (SSRIs), such as sertraline, fluoxetine, and paroxetine, which selectively block the reuptake of serotonin;
- Serotonin and norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, duloxetine, and milnacipran, which selectively block the reuptake of serotonin and norepinephrine;
- Monoamine oxidase inhibitors (MAOIs) such as phenelzine, which cause an accumulation of amine neurotransmitters and are not commonly used, owing to the adverse reactions with concomitant medications and various food groups; and
- Tricyclic antidepressants (TCAs), like nortriptyline, which are antimuscarinic drugs that block the reuptake of both serotonin and norepinephrine and have variable sedative properties.

The applicant indicated that non-pharmacological treatments, such as psychotherapies, including cognitive behavioral therapy, psychosocial community-based intervention, and dynamic therapy have also been used to treat PPD.

Based on market research conducted by the applicant, the applicant asserted that current treatment options for patients who have been diagnosed with PPD present potential challenges for patients such as: Long wait times for an appointment and difficulties scheduling follow-up appointments with providers; insurance coverage challenges; delays or interruptions in treatment; changes in medications or doses (which may or may not be effective): And the lengths of the treatment plan being longer than expected.

With respect to the newness criterion, FDA granted ZULRESSO™ Priority Review and Breakthrough Therapy designations, and on March 19, 2019, approved ZULRESSO™ for the treatment of PPD in adult women. On June 17, 2019, the Drug Enforcement Administration (DEA) placed ZULRESSO™ into Schedule IV of the Controlled Substances Act (84 FR 27938 through 27943), after which it became commercially available. The applicant submitted a request for approval for two unique ICD–10–PCS procedure codes for the administration of ZULRESSO™ beginning in FY 2021 and was granted approval for the following procedure codes effective October 1, 2020: XW03306 (Introduction of Brexanolone into peripheral vein, percutaneous approach, new technology group 6) and XW04306 (Introduction of Brexanolone into central vein, percutaneous approach, new technology group 6).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, ZULRESSO™ does not use the same or a similar mechanism of action when compared to existing treatments. The applicant indicated that

[401] Kanes, SJ, Colquhoun, H, Doherty, J, Raines, S, Hoffmann, E, Rubinow, DR, Meltzer-Brody, S. ''Open-label, proof-of-concept study of brexanolone in the treatment of severe postpartum depression,'' *Human Psychopharmacology: Clinical & Experimental,* 2017, Vol. 32(2).

[402] Lüscher, B, Möhler, H, ''Brexanolone, a neurosteroid antidepressant, vindicates the GABAergic deficit hypothesis of depression and may foster resilience,'' *F1000Research,* 2019, vol. 751.

prior to the approval of ZULRESSO™, certain antidepressants were prescribed for the treatment of PPD; however, these antidepressants are not specifically indicated for PPD. In addition, the applicant asserted that ZULRESSO™ does not use the same or a similar mechanism of action as current antidepressants, including SSRIs, SNRIs, MAOIs, and TCAs. The applicant stated that ZULRESSO™ works differently because it does not directly affect monoaminergic systems, with the mechanism of action believed to be related to ZULRESSO™'s positive allosteric modulation of $GABA_A$ receptors. Therefore, the applicant asserted that ZULRESSO™ utilizes a different mechanism of action than currently available treatment options.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the antidepressants and non-pharmacological treatments historically used to treat PPD are traditionally used in the outpatient setting; however, patients with more severe symptoms of PPD who are hospitalized would likely have the same diagnosis (F53.0—Postpartum depression) and be assigned to the same MS–DRG as ZULRESSO™ patients, MS–DRG 881 (Depressive Neuroses).

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the use of ZULRESSO™ for treating PPD would involve treatment of a similar patient population as compared to other therapies historically used to treat PPD. However, the applicant noted that there are no other treatments or technologies that are specifically indicated for the treatment of PPD.

As summarized previously, the applicant maintains that ZULRESSO™ meets the newness criterion and is not substantially similar to existing technologies because it has a unique mechanism of action for treating PPD and is the only therapy specifically indicated for the treatment of PPD. We invited public comments on whether ZULRESSO™ is substantially similar to any existing technologies and whether ZULRESSO™ meets the newness criterion.

Comment: The applicant submitted a comment reiterating that ZULRESSO™ meets the newness criterion and is not substantially similar to existing technologies because ZULRESSO™ does not use the same or a similar mechanism of action as the antidepressants commonly prescribed to treat PPD. The applicant stated that ZULRESSO™ works differently than these antidepressants because it does not directly affect monoaminergic systems, with the mechanism of action believed to be related to ZULRESSO™'s positive allosteric modulation of $GABA_A$ receptors. The applicant also asserted that ZULRESSO™ meets the newness criterion because it does not involve the treatment of the same or similar type of disease and the same or similar patient population because ZULRESSO™ is the first and only therapy specifically indicated to treat adult patients with PPD.

Response: Based on the applicant's comment and information submitted by the applicant as part of its FY 2021 new technology add-on payment application for ZULRESSO™, as discussed in the proposed rule (85 FR 32673) and previously summarized, we disagree that the use of the technology does not involve the treatment of the same or similar type of disease and the same or similar patient population as existing technologies. As noted by the authors of the Phase III study submitted by the applicant, PPD is considered a subtype of major depression in the DSM–5 and the International Classification of Diseases.[403] Given that there are antidepressants indicated for treating major depressive disorders (of which PPD is a subtype) that are currently being used to treat PPD, we believe there are existing technologies available to treat patients with PPD. However, we agree with the applicant that ZULRESSO™ does not use the same or a similar mechanism of action to achieve a therapeutic outcome when compared to existing treatments. Therefore, we believe that ZULRESSO™ is not substantially similar to an existing technology and meets the newness criterion. We consider the beginning of the newness period to commence when the DEA placed ZULRESSO™ into Schedule IV of the Controlled Substances Act on June 17, 2019, after which it became commercially available.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Hospital Limited Data Set (LDS) to determine the MS–DRGs to which cases representing potential patient hospitalizations that may be eligible for treatment involving ZULRESSO™ may be assigned. The applicant identified these potential cases as those with a principal or secondary diagnosis code of F53 (Puerperal psychosis), excluding MA cases and claims submitted only for GME payment. The applicant noted that ICD–10–CM diagnosis code F53.0 (Postpartum depression) became effective October 1, 2018, and was not found on any FY 2018 inpatient claims. The applicant identified 76 cases reporting ICD–10–CM diagnosis code F53.0 spanning 26 different MS–DRGs, with approximately 58 percent of these potential cases mapping to the following 3 MS–DRGs, out of which approximately 49 percent of those potential cases mapped to the top 2 MS–DRGs:

MS-DRG	MS-DRG Title
MS-DRG 776	Postpartum and Post Abortion Diagnoses without O.R. Procedure
MS-DRG 807	Vaginal Delivery without Sterilization/D&C without CC/MCC
MS-DRG 885	Psychoses

The applicant did not remove charges for the prior technology or the technology being replaced because the historical treatment regimens, such as oral anti-depressants, do not need to be stopped during treatment with ZULRESSO™. The applicant also noted that ZULRESSO™ is the first and only FDA-approved treatment specifically indicated for PPD so there are no prior technology charges to remove. The applicant then standardized the FY 2018 charges using the FY 2018 impact file and inflated the charges to FY 2020 using the 2-year inflation factor of 11.1

[403] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

percent (1.11100) published in the FY 2020 IPPS/LTCH PPS final rule (see 84 FR 42629). The applicant then added charges for ZULRESSO™, based on the average per discharge cost of ZULRESSO™ inflated by the inverse of the national average CCR for pharmacy costs of 0.189. The applicant calculated a final average case-weighted standardized charge per case of $225,056. Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the applicant calculated an average case-weighted threshold amount of $33,012. The applicant stated that ZULRESSO™ exceeded the average-case-weighted threshold amount and, therefore, meets the cost criterion.

As noted previously, the 76 cases reporting ICD–10–CM diagnosis code F53.0 span 26 different MS–DRGs, with very few observations in most of these MS–DRGs. We noted in the proposed rule that a sub-analysis of the top 2 MS–DRGs—which represent 49 percent of the cases—would still exceed the threshold. We also noted that a sub-analysis assigning 100 percent of the cases to the highest paying of these 26 MS–DRGs would also still exceed the threshold.

We stated in the proposed rule that we are concerned with the limited number of cases in the sample the applicant analyzed. However, we acknowledged the difficulty in obtaining cost data for a condition that has low prevalence in the Medicare population. We invited public comments on whether ZULRESSO™ meets the cost criterion.

Comment: The applicant submitted a comment asserting that, as demonstrated in its application, ZULRESSO™ meets the cost criterion, despite the low volume, and the applicant noted that CMS has approved new technology add-on payment for other low volume procedures. The applicant also raised the possibility that the implementation of a new ICD–10–CM code for PPD in October 2018 might have led to underreporting of the diagnosis code in the data available for analysis.

Response: Based on the applicant's comment and information submitted by the applicant as part of its FY 2021 new technology add-on payment application for ZULRESSO™, as discussed in the proposed rule (85 FR 32673 through 32674) and previously summarized, the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, ZULRESSO™ meets the cost criterion.

With regard to substantial clinical improvement, the applicant asserted that, because there is no other treatment option specifically approved by FDA to treat PPD, ZULRESSO™ represents a substantial clinical improvement over existing technologies. In support of this statement, the applicant submitted the FDA approval letter and news release indicating that the approval of ZULRESSO™ marks the first time a drug has been specifically approved to treat PPD.[404] The applicant also asserted that ZULRESSO™ represents a substantial clinical improvement because the technology significantly reduces depressive symptoms and improves patients' functioning. The applicant submitted three studies to support its assertion that ZULRESSO™ represents a substantial clinical improvement over existing technologies by improving depressive symptoms and patients' functioning.

The first study submitted (202A) was a Phase II, multicenter, randomized, double-blind, parallel-group, placebo-controlled clinical trial with 30-day follow-up in women diagnosed with severe PPD. Patients with severe PPD (n=21) were randomized to receive a single, continuous intravenous infusion of ZULRESSO™ or placebo for 60 hours. The primary endpoint was the change from baseline in the 17-item Hamilton Depression Rating Scale (HAM–D) total score at the end of the 60-hour treatment period, compared to placebo. At the end of the 60-hour intravenous infusion, the least-squared (LS) mean reduction in HAM–D total score from baseline was 21.0 points in the ZULRESSO™ group compared with 8.8 points in the placebo group. The researchers concluded that in women with severe PPD, infusion of ZULRESSO™ resulted in a significant and clinically meaningful reduction in HAM–D total score, compared with placebo.[405]

The second and third studies submitted (202B and 202C) were Phase III, multicenter, randomized, double-blind, parallel-group, placebo-controlled clinical trials with 30-day follow-up conducted at 30 clinical research centers and specialized psychiatric units in the United States. The studies included women between the ages of 18–45 years, 6 months postpartum or less at screening, with PPD and a qualifying score on the HAM–D. In both studies, patients were randomly assigned to receive a single, continuous 60-hour intravenous infusion of ZULRESSO™ or matching placebo. The primary endpoint in both studies was the change from baseline in the 17-item HAM–D total score at 60 hours, compared with placebo. Study 202B consisted of patients who were diagnosed with severe PPD (HAM–D score ≥26) who were randomly assigned to receive a single intravenous infusion of either ZULRESSO™ 90 μg/kg per h (BRX90), ZULRESSO™ 60 μg/kg per hour (BRX60), or matching placebo for 60 hours. Study 202C consisted of patients who were diagnosed with moderate PPD (HAM–D score of 20 to 25) who were randomly assigned to BRX90 or matching placebo for 60 hours. Three hundred and seventy-five women were simultaneously screened across both studies, of whom 138 were randomly assigned to receive either BRX90 (n=45), BRX60 (n=47), or placebo (n=46) in Study 202B, and 108 were randomly assigned to receive BRX90 (n=54) or placebo (n=54) in Study 202C. In study 202B, at hour 60, the LS mean reduction in HAM–D total score from baseline was 19.5 points in the BRX60 group and 17.7 points in the BRX90 group, compared with 14.0 points in the placebo group. In Study 202C, at hour 60, the LS mean reduction in HAM–D total score from baseline was 14.6 points in the BRX90 group compared with 12.1 points for the placebo group. The researchers concluded that administration of ZULRESSO™ for PPD resulted in significant and clinically meaningful reductions in HAM–D total score at hour 60 compared with placebo, with rapid onset of action and durable treatment response during the study period of 30 days.[406]

The applicant provided data from the clinical studies cited previously to support that ZULRESSO™ improves patients' depressive symptoms as measured by a reduction in the HAM–D score at hour 60, and sustained at day 30. The applicant cited data from the Phase II study (202A) that, at the end of the 60-hour infusion, the LS mean

[404] Food and Drug Administration, ''FDA approves first treatment for post-partum depression,'' *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-post-partum-depression.*

[405] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet.* 2017,vol. 390(10093), pp. 480–489.

[406] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

reduction in HAM–D total score was significantly larger for the ZULRESSO™ (90 μg/kg/h) group compared with the placebo group (21.0 vs 8.8 points, respectively). Prespecified secondary analyses showed a mean difference of –11.3 points between groups as early as 24 hours after infusion, with significant improvements also seen for the ZULRESSO™ group at 36, 48, 60, and 72 hours, as well as days 7 and 30. A greater percentage of patients in the ZULRESSO™ group achieved a treatment response (defined as ≥50% reduction from baseline in HAM–D total score) compared to the placebo group, with a significant difference observed at hour 72 (80% vs. 27%) and day 7 (80% vs. 20%). At hour 60, 70 percent of patients in the ZULRESSO™ group and 36 percent of patients in the placebo group had a treatment response. A greater percentage of patients treated with ZULRESSO™ achieved remission (HAM–D total score ≤7) at hour 60 compared with the placebo group (70.0% vs. 9.1%). The difference was significant at hours 24, 48, 60, and 72, and days 7 and 30.[407]

The applicant cited data from the Phase III multicenter study of patients with severe PPD (202B) that at hour 60, and sustained at day 30, the LS mean reduction in HAM–D total score was significantly greater for the ZULRESSO™ groups, compared to the placebo groups. At hour 60, the LS mean reduction in HAM–D total score was 17.7 points in the BRX90 group and 19.5 points in the BRX60 group, compared to 14.0 points in the placebo group. At all-time points from hour 24 to day 30, the percentage of patients achieving HAM–D response (≥50% reduction from baseline in HAM–D total score) was higher in both ZULRESSO™ groups compared with placebo, with statistical significance achieved for both ZULRESSO™ groups across multiple timepoints compared with placebo. The percentage of patients achieving HAM–D remission (total score ≤7) was numerically higher in both ZULRESSO™ groups between 24 and 72 hours and at day 30 compared with the placebo group.[408]

The applicant cited data from the Phase III multicenter study of patients with moderate PPD (202C) that at the end of the 60 hour infusion, the LS mean reduction in HAM–D total score was significantly greater in the ZULRESSO™ BRX90 group compared with the placebo group (14.6 vs 12.1, respectively). At all time points from hour 8 through day 14, the percentage of patients achieving HAM–D remission (total score ≤7) was numerically higher for the ZULRESSO™ BRX90 group compared with the placebo group, with statistical significance achieved at multiple time points, including at the end of the 60 hour infusion.[409]

The applicant cited pooled data from the ZULRESSO™ BRX90 groups in the Phase II (202A) and Phase III (202B and 202C) studies showing a significant LS mean reduction in HAM–D total score compared with the placebo group at hour 60 (17.0 vs 12.8 points). Similar to the individual studies, the integrated BRX90 analysis showed a rapid decrease in HAM–D scores (that is, depressive symptoms) in the BRX90 group compared with the placebo groups, which was sustained until day 30. At the end of the 60 hour infusion, the LS mean reduction in HAM–D total score from baseline was significantly larger in the BRX90 group than the placebo group (LS mean difference -4.1), which was also observed at 24 hours (LS mean difference -3.0) and was sustained at day 30 (LS mean difference -2.6).[410]

The applicant provided data from the clinical studies cited previously to support that ZULRESSO™ improves patients' functioning scores, as measured by the Clinical Global Impressions Scale-Improvement (CGI–I). The applicant cited data from the Phase II study (202A) that the observed improvement in symptoms of postpartum depression following ZULRESSO™ administration was evidenced by the significant treatment difference observed for CGI–I response. At day 30, 3 (27.3%) patients in the placebo group vs. 8 (80.0%) patients treated with ZULRESSO™ were considered CGI–I responders with a score of ''1—very much improved'' or ''2—much improved''.[411]

The applicant cited data from the Phase III study of patients with severe PPD (202B) that patients' functioning scores, as measured by CGI–I, improved at hour 60, and sustained at day 30. The proportion of patients who achieved a CGI–I response (score of ''1—very much improved,'' or ''2—much improved'') at 60 hours was significantly higher in both ZULRESSO™ groups. The proportion of BRX90 patients who achieved a CGI–I response was also significantly higher than the placebo group at hour 72 and day 30 and significantly higher in the BRX60 group compared to placebo at timepoints from hours 36 to 72 and days 7 and 30.[412]

The applicant cited data from the Phase III study of patients with moderate PPD (202C) that the proportion of patients who achieved a CGI–I response was significantly higher for the BRX90 group compared with the placebo group at hour 60. These significant increases in CGI–I response occurred as early as 36 hours and were sustained at day 7.[413]

The applicant provided data from the clinical studies cited previously to support that ZULRESSO™ improves patients' depressive symptoms, as measured by the Montgomery-Asberg Depression Rating Scale (MADRS). The applicant cited data from the Phase II study (202A) that ZULRESSO™ improved patients' depressive symptoms, as measured by the MADRS, at hour 60 and sustained at day 30. Through the study period, patients in the ZULRESSO™ (90 μg/kg/h) group showed significant differences in MADRS score compared with the placebo group (hour 24, P=0.004; hour 60, P=0.01; day 30, P=0.01).[414]

The applicant cited data from the Phase III study of patients with severe PPD (202B) that ZULRESSO™ improved patients' depressive symptoms, as measured by the MADRS, at hour 60. Numerically greater improvement from baseline in MADRS total score was observed for both ZULRESSO™ (60 μg/kg/h and 90 μg/kg/h) treatment groups compared with the

[407] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet.* 2017,vol. 390(10093), pp. 480–489.

[408] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[409] Ibid.

[410] Ibid.

[411] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet.* 2017,vol. 390(10093), pp. 480–489.

[412] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[413] Ibid.

[414] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet.* 2017,vol. 390(10093), pp. 480–489.

placebo group at hour 60 and day 30. This difference was statistically significant at hour 60 for ZULRESSO 60 μg/kg/h (LS mean difference vs placebo, −6.9).[415]

The applicant cited data from the Phase III study of patients with moderate PPD (202C) that ZULRESSO™ improved patients' depressive symptoms, as measured by the MADRS, at hour 60. There was a statistically significant improvement from baseline in the MADRS total score for the ZULRESSO™ (90 μg/kg/h) group compared to placebo at hour 60 (LS mean difference vs. placebo, −4.9).[416]

The applicant cited data from the Phase II study (202A) cited previously that ZULRESSO™ improves patients' depressive symptoms as measured by the Bech-6 Subscale, a secondary endpoint. In the Phase II study (202A), significant improvement in the core depressive symptoms of the HAM–D Bech-6 Subscale score were observed at day 30 in the ZULRESSO™ (90 μg/kg/h) group compared with the placebo group.[417]

We stated in the proposed rule that after reviewing the information submitted by the applicant as part of its FY 2021 new technology add-on payment application for ZULRESSO™, we are concerned that the patients in the clinical trials were followed up for only 30 days, and the durability of the effects of ZULRESSO™, including whether patients in remission relapse after 30 days, is not clear. We also noted that the small sample sizes of the trials and the demographic characteristics of the patients recruited for these studies may not have included or sufficiently represented populations that may be at high-risk to develop PPD, such as women who are financially or socially vulnerable and individuals with pre-existing mental illness, and it is not clear whether the study participants had time-limited PPD that might have resolved with the passage of time. We stated that it is also unclear whether the outcomes chosen for these studies (for example, test scores) translate into clinically significant observable improvements in maternal functioning and child interactions; for example, has maternal-child bonding been shown to improve as a result of the infusion. We also noted that these studies compare the effects of ZULRESSO™ to placebo, and not current regimens being used to treat PPD, and do not seem to include patients who were unresponsive to existing therapies. In addition, we stated that we are concerned whether results of studies of otherwise healthy women with PPD would be generalizable to the Medicare population, in which women with PPD would likely be eligible for Medicare based on disabilities that could potentially present comorbidities for which ZULRESSO™ would not be appropriate or effective. We also noted that because of possible side effects of excessive sedation or sudden loss of consciousness, ZULRESSO™ is only available through a restricted Risk Evaluation and Mitigation (REMS) program, and stated that we are concerned whether these or other adverse events associated with ZULRESSO™ would be unsafe for women with PPD in the Medicare population. We invited public comments on whether ZULRESSO™ meets the substantial clinical improvement criterion, including with respect to the concerns we have raised.

Comment: We received public comments, including additional information submitted by the applicant, in response to CMS's concerns in the proposed rule regarding whether ZULRESSO™ meets the substantial clinical improvement criterion.

With respect to the concern that the patients in the clinical trials were followed up for only 30 days, and the durability of the effects of ZULRESSO™, including whether patients in remission relapse after 30 days, is not clear, the applicant stated that the 30-day follow-up period was accepted by FDA as an appropriate follow-up period for women with PPD enrolled in the ZULRESSO™ studies. The applicant explained further that the clinical trials were designed to enroll women diagnosed with PPD, and DSM–5 defines PPD as a major depressive episode with symptom onset during pregnancy or in the first 4 weeks following delivery. As such, if a patient achieves remission after being successfully treated in the postpartum and then experiences a relapse episode beyond 4 weeks, this may no longer meet the DSM–5 definition of PPD. The applicant also stated that due to the rapidity of the treatment effect observed with ZULRESSO™ at 60 hours in the phase 2 trial (202A), it was determined in conjunction with FDA that 30 days was an appropriate follow-up period for the ZULRESSO™ studies. The applicant acknowledged that the efficacy and safety of ZULRESSO™ beyond 30 days has not been evaluated. The applicant also acknowledged that there is limited data in PPD, though the applicant referenced studies that per the applicant show that an improvement of depressive symptoms as early as 2 weeks after treatment initiation may be a predictor of achieving stable response and remission for patients with major depressive disorders, and referenced other studies that per the applicant suggest that failure to treat depressive episodes rapidly and effectively to remission may have long-term negative effects. The applicant noted that the effects of ZULRESSO™ were sustained through Day 30, and the applicant cited data from the integrated Phase III analysis that 94% of patients who received BRX90 and had a HAM–D response at hour 60 did not relapse at Day 30.[418] One commenter asserted that the 30-day timeframe is an essential component of preserving the immediate long-term health and wellbeing of many postpartum women and their infants, as per the commenter it is around this timeframe that postpartum women bond with their infants, initiate or choose to continue breastfeeding, and navigate and receive treatment for other postpartum health complications.

With respect to the concern that the small sample sizes of the trials and the demographic characteristics of the patients recruited for these studies may not have included or sufficiently represented populations that may be at high-risk to develop PPD, the applicant stated that the sample sizes were developed in conjunction with FDA based on FDA guidelines for designing trials with sufficient statistical power to detect the anticipated treatment effect and safety of drugs being developed to treat major depressive disorders. The applicant also stated that in the Phase III studies, ZULRESSO™ demonstrated a statistically significant improvement in depressive symptoms at hour 60 across a diverse patient population, and the applicant highlighted some of the subgroups who are at high-risk of developing PPD that were represented in the Phase III studies. Further, the applicant stated that in study 202B of

[415] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[416] Ibid.

[417] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet.* 2017,vol. 390(10093), pp. 480–489.

[418] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

patients with severe PPD, 47% of patients treated with BRX90 had a personal history of depression, and 47% had a history of anxiety. The applicant noted that in study 202C of patients with moderate PPD, patients with a personal history of depression and anxiety accounted for 24% and 31% of patients respectively. The applicant also noted that, in both Phase III studies, approximately ⅓ of patients had a family history of PPD, with 27% in 202B and 35% in 202C experiencing a previous episode of PPD. Per the applicant, subgroup analyses showed greater LS mean differences in HAM–D total score at hour 60 in the BRX90 group compared with the placebo group from baseline in all subgroups examined for ethnicity, personal history of PPD, a family history of PPD or major depressive disorders.[419]

With respect to the concern whether study participants had time-limited PPD that might have resolved with the passage of time, the applicant stated that untreated PPD may not resolve with time. The applicant referenced studies of major depressive disorders that, per the applicant, show that duration of untreated depression correlates with worse outcomes. The applicant also referenced studies that, per the applicant, suggest that symptoms that may have begun as PPD may persist throughout and beyond the first postnatal year if left untreated.

With respect to the concern whether the outcomes chosen for these studies translate into clinically significant observable improvements in maternal functioning and child interaction, the applicant explained that they selected change in baseline HAM–D scale as the primary endpoint because it is validated, reliable, and accepted by FDA as a primary efficacy endpoint in a patient population with depression, and they selected the CGI–I scale because is accepted by FDA as a secondary endpoint to measure other domains of symptom improvement. The applicant acknowledged that there is no specific data related to ZULRESSO™ with respect to maternal functioning and long term child development. However, the applicant asserted that improving depressive symptoms in mothers with PPD may translate into clinically significant and observable improvements in maternal functioning and child interactions, and the applicant referenced various studies that found associations between maternal PPD symptoms and impairments to maternal bonding and multiple aspects of child development and functioning. The applicant also referenced studies that, per the applicant, show significant improvements in child development and functioning after successfully treating women with maternal depression.

With respect to the concern that these studies compare the effects of ZULRESSO™ to placebo, and not current regimens being used to treat PPD, and do not seem to include patients who were unresponsive to existing therapies, the applicant stated that the ZULRESSO™ clinical development program was designed in accordance with FDA and aligns to current guidance related to developing drugs to treat major depressive disorders. In referencing these guidelines, the applicant noted that these guidelines provide that the standard for such trials include randomized, double-blinded, placebo controlled, parallel short-term efficacy trials in patients with depression. The applicant also noted that patients with a history of PPD and non-PPD depression were included across all placebo-controlled studies. Patients who were taking antidepressants at a stable dose for at least 14 days prior to enrollment were allowed to participate in the ZULRESSO™ clinical trials if they met other inclusion/exclusion criteria. The applicant noted that across both phase III trials 22% of patients had baseline antidepressant use and either a HAM–D score between 20–25 (moderate depression) or greater than 26 (severe depression). Per the applicant, subgroup analyses at hour 60 also showed statistically significant LS mean differences in change from baseline in all subgroups examined, including baseline antidepressant use.[420] One commenter agreed that the existing evidence base for the use of ZULRESSO™ as a treatment for PPD is limited but believes that the existing studies on ZULRESSO™ satisfy the clinical improvement criteria. The commenter stated that there is a dearth of evidence available on the effectiveness of other treatments for PPD, and the commenter noted that the studies demonstrated that improvements for those who received ZULRESSO™ were significantly greater than the improvements shown by the placebo group.

With respect to the concern whether the results of the studies would be generalizable to the Medicare population, the applicant believes that these results can be generalized to the patient population that qualifies for Medicare due to disability. The applicant stated that two of the first patients that were treated with ZULRESSO™ since it became commercially available were dual-eligible beneficiaries. The applicant also observed that as with any drug or procedure, ZULRESSO™ may not be appropriate for every patient, and decisions regarding its use should be made between the patient and their healthcare provider based on the risks and benefits of treatment.

With respect to the concern whether the adverse events associated with ZULRESSO™ would be unsafe for women with PPD in the Medicare population, the applicant stated that the safety precautions that are in place for women with PPD being treated with ZULRESSO™, including the restrictive program requirements of the ZULRESSO™ REMS, would apply to patients from both the general and Medicare population. The applicant also stated that as with any treatment, the prescriber should use his or her clinical judgment whether ZULRESSO™ is an appropriate treatment option for PPD and discuss the risks and benefits, including reviewing the Patient Information Guide with the patient.

We also received other public comments urging CMS to approve the application for new technology add-on payment for ZULRESSO™, stating it alleviates symptoms of PPD within hours or days, rather than the weeks that may be required to relieve symptoms using other regimens that are prescribed to treat post-partum women with PPD. One commenter stated that mothers and providers have reported positive outcomes from the use of ZULRESSO™ and submitted examples of these reports. Commenters noted that ZULRESSO™ is not currently widely available to women despite being FDA-approved, and they suggested that hospitals may be unwilling to provide this treatment due to its cost. Commenters observed that state Medicaid programs and private health insurers often base their coverage and payment policies off of those established by CMS for Medicare. Commenters expressed concern that without approval of the new technology add-on payment application for ZULRESSO™, women could be denied access to the only FDA-approved treatment specifically indicated to treat PPD, with some commenters adding that all FDA-approved treatments should be readily accessible to women experiencing PPD.

Response: We thank the commenters for their input and responses to our concerns, and we appreciate the

[419] Ibid.

[420] Ibid.

additional information the applicant provided with regard to the safety and efficacy of ZULRESSO™ in reducing depressive symptoms rapidly and significantly when compared to placebo. Although commenters asserted that ZULRESSO™ starts to work more rapidly than other treatments, we remain concerned that the studies and additional information submitted by commenters do not provide sufficient evidence to determine that the use of ZULRESSO™ represents a substantial clinical improvement when compared to existing treatments.

We remain concerned that all of the studies submitted by the applicant used placebo as control and did not compare the use of ZULRESSO™ to the use of existing treatments. As noted by the applicant in their comments, patients who were taking antidepressants at a stable dose for at least 14 days prior to enrollment were allowed to participate in the ZULRESSO™ clinical trials if they met other inclusion/exclusion criteria, and analysis of this subgroup showed statistically significant LS mean differences in change in HAM–D at hour 60 compared to baseline.[421] Given that these Phase III studies were not designed to compare the use of ZULRESSO™ to currently available treatments, we do not believe that the analysis of a subgroup is sufficient evidence that the use of ZULRESSO™ provides a substantial clinical improvement over the use of existing technologies, especially since traditional antidepressants may take 4–6 weeks to have full therapeutic effect (not 14 days). We also note that there are multiple medications approved to treat major depressive disorders (of which PPD is a subtype), and it is unclear whether there was uniformity in the type or dosage of antidepressant used by this subgroup in the Phase III studies that could suggest that the use of ZULRESSO™ represents a substantial clinical improvement over a specific regimen of antidepressant medications used to treat PPD.

With regard to the superiority of ZULRESSO™ versus placebo, the primary endpoint of improvement in HAM–D scores from baseline at the conclusion of the 60-hour infusion was met in both Phase III studies submitted by the applicant, demonstrating the efficacy of the use of ZULRESSO™ in rapidly reducing depressive symptoms compared with placebo at this timepoint (60-hour infusion). However, we note that the study authors observed variable placebo response across the three placebo-controlled trials, with robust placebo response in studies 2 and 3. For example, in the third study, placebo had a stronger effect than treatment at 30 days. We also note that the secondary endpoint of HAM–D remission at 30 days was not statistically significant in any of the treatment groups or in the integrated analysis when compared to placebo.[422]

We also remain concerned over the durability of the effects of ZULRESSO™ beyond the 30-day follow-up period. As noted by the study authors, an important limitation of these trials is that the effects of ZULRESSO™ after the 30-day follow-up period are unknown. We believe that this is particularly important since ZULRESSO™ is a one-time infusion while other antidepressants are continued long-term. In addition, data on the effectiveness of current antidepressants in post-partum women are scarce so the long-term efficacy of the use of ZULRESSO™ compared with currently available oral antidepressants is unclear.[423]

We also remain concerned as to whether study participants had time-limited PPD that might have resolved with the passage of time and whether the outcomes chosen for these studies translate into clinically significant observable improvements in maternal functioning and child interaction.

After consideration of all the information from the applicant, as well as the public comments we received, we are unable to determine that ZULRESSO™ represents a substantial clinical improvement over existing technologies, and we are not approving new technology add-on payments for ZULRESSO™ for FY 2021.

6. FY 2021 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program or a product is designated by FDA as a Qualified Infectious Disease Product (QIDP), and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still meet the cost criterion.

We received 10 applications for new technology add-on payments for FY 2021 under this alternative new technology add-on payment pathway. One applicant withdrew its application prior to the issuance of the proposed rule. Of the remaining nine applications, three of the technologies received a Breakthrough Device designation from FDA and six have been designated as a QIDP by FDA. In accordance with the regulations under § 412.87(e), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. While we do not typically address in the final rule those applications for which the technology has not received FDA approval for the relevant indication by the July 1 deadline, we are summarizing and responding to comments we received regarding whether the applicant for the NanoKnife System® received the required FDA marketing authorization for this product by July 1. A discussion of these remaining nine applications is presented in this final rule.

Typically, in the annual proposed rule, we provide a summary of each application and describe any concerns we may have regarding whether the technology meets a specific new technology add-on payment criterion. As we discussed in the FY 2020 IPPS/LTCH PPS final rule, we believe it is appropriate to facilitate access to these transformative new technologies and antimicrobials as part of the Administration's commitment to addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes. To that end, to provide additional transparency and predictability with respect to these technologies, in the FY 2021 IPPS/LTCH PPS proposed rule we proposed to approve or disapprove each of these nine applications based on whether the technology met the cost criterion. In this section of this final rule, we discuss whether or not each technology will be eligible for the new technology add-on payment for FY 2021. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) for a complete discussion of the alternative new technology add-on payment pathways for these technologies.

[421] Ibid.

[422] Ibid.

[423] Ibid.

a. Alternative Pathway for Breakthrough Devices

(1) BAROSTIM NEO® System

CVRx submitted an application for the BAROSTIM NEO® System. According to the applicant, the BAROSTIM NEO® System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤35%, a NT-proBNP <1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

The BAROSTIM NEO® System received FDA approval on August 16, 2019 and is a Breakthrough Device designated by FDA. Additionally, according to the applicant, the device was available on the market immediately upon FDA approval. Currently, the following ICD–10–PCS procedure codes can be used to uniquely identify the BAROSTIM NEO® System: 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK0MZ (Insertion of stimulator lead into right internal carotid artery, open approach) or 03HL0MZ (Insertion of stimulator lead into left internal carotid artery, open approach).

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving the BAROSTIM NEO® System would mapped. The applicant searched for cases with the following combination of existing ICD–10–PCS codes: 0JH60MZ in combination with 03HK0MZ or 03HL0MZ. The applicant determined its search using these procedure codes mapped to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively), resulting in 71,431 total claims across these three MS–DRGs.

The applicant then removed charges for the prior technology since the BAROSTIM NEO® System will replace all of the current device charges included in the claims. The applicant explained that it removed all charges associated with the service category Medical/Surgical Supply Charge Amount, which include revenue centers 027x.

The applicant then standardized the charges and inflated the charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant then added the charges for the new technology by converting the cost of the device to charges by dividing the costs by the national average cost-to-charge ratio of 0.299 for implantable devices from the FY2020 IPPS Final Rule (84 FR 42179).

Based on the previous information, the applicant calculated a final average case-weighted standardized charge per case of $194,393 and an average case-weighted threshold of $85,559. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

According to the applicant, since the BAROSTIM NEO® System is used in heart failure patients, the applicant submitted an additional analysis to demonstrate that the technology meets the cost criterion. The applicant revised its first analysis by assessing MS–DRG 291 (Heart Failure and Shock with MCC), 292 (Heart Failure and Shock with CC), and 293 (Heart Failure and Shock without CC/MCC), 242 (Permanent Cardiac Pacemaker Implant with MCC), 243 (Permanent Cardiac Pacemaker Implant with CC), 244 (Permanent Cardiac Pacemaker Implant without CC/MCC), 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC), 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC), 224 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC), 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC), 226 (Cardiac Defibrillator Implant without Cardiac Catheterization with MCC) and 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without MCC) using the same aforementioned ICD–10–PCS codes. The applicant used the same methodology, as previously indicated and calculated a final inflated average case-weighted standardized charge per case of $161,332 and an average case-weighted threshold amount of $55,697. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

In the proposed rule, we stated that we agree with the applicant that the BAROSTIM NEO® System meets the cost criterion and therefore proposed to approve the BAROSTIM NEO® System for new technology add-on payments for FY 2021. As previously noted, there is a combination of ICD–10–PCS procedure codes that can uniquely identify cases involving the BAROSTIM NEO® System.

Based on information from the applicant at the time of the proposed rule, the cost of the BAROSTIM NEO® System is $35,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the BAROSTIM NEO® System would be $22,750 for FY 2021(that is 65 percent of the average cost of the technology).

We invited public comments on whether the BAROSTIM NEO® System meets the cost criterion and our proposal to approve new technology add-on payments for the BAROSTIM NEO® System for FY 2021.

Comment: A commenter, the applicant, supported CMS' proposal to approve new technology add-on payments for FY 2021 for BAROSTIM NEO® System.

Response: We appreciate the applicant's support.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the BAROSTIM NEO® System meets the cost criterion. The BAROSTIM NEO® System received marketing authorization from the FDA on August 16, 2019 for the indication covered by its Breakthrough Device designation.

Therefore, we are finalizing our proposal to approve new technology add-on payments for BAROSTIM NEO® System for FY 2021, and we consider the beginning of the newness period to commence on August 16, 2019 which is when the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. Under § 412.88(a)(2)(ii)(A), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing a maximum new technology add-on payment of $22,750 for a case involving the use of the BAROSTIM NEO® System for FY 2021 (that is 65 percent of the average cost of the technology). Cases involving the use of

BAROSTIM NEO® System that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: 0JH60MZ in combination with 03HK0MZ or 03HL0MZ.

(2) The NanoKnife® System

Angiodynamics submitted an application for new technology add-on payments for the NanoKnife® System for FY 2021. The applicant is seeking new technology-add on payments for the use of the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer. We noted in the proposed rule that FDA has not yet granted market approval of the NanoKnife® System for use in the treatment of pancreatic cancer. We also noted that the NanoKnife® System has been previously approved by FDA for the use for surgical ablation of soft tissue. Per the applicant, the Nanoknife® System is a medical device consisting of a dedicated generator and specialized electrode probes currently used for inpatient hospital ablation procedures for surgical treatment of soft tissue ablation procedures. The NanoKnife® System is considered a FDA class II device when indicated for soft tissue ablation.

The applicant stated that the NanoKnife® System delivers a series of high voltage direct current electrical pulses between at least two electrode probes placed within a target area of tissue. The electrical pulses produce an electric field which induces electroporation on cells within the target area. The number of electrodes used is dependent on the size and shape of the tumor, and the individual patient's clinical needs.

According to the applicant, electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. The result is creation of nanopores in the cell membrane and disruption of intracellular homeostasis, ultimately causing cell death. The applicant stated that after delivering a sufficient number of high voltage pulses, the cells surrounded by the electrodes will be irreversibly damaged. This mechanism, which causes permanent cell damage, is referred to as Irreversible Electroporation (IRE). Per the applicant, benefits of IRE over other ablation methods include: (1) Localized ablation of targeted tissue; (2) lack of damaging heat-sink effect often seen with traditional thermal ablation techniques; and (3) preservation of critical anatomic structures in the vicinity of the ablation. Furthermore, according to the applicant, in studies to date, the NanoKnife® System has been shown to be safe and effective in patients presenting with unresectable tumors, who, given current treatment standards, have few viable treatment options.

The NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer received FDA Breakthrough Device designation on January 18, 2018 and approval of an FDA investigational device exemption (IDE G180278) on March 28, 2019. We noted in the proposed rule, as discussed previously, that although the NanoKnife® System received FDA Breakthrough Device designation for treatment of pancreatic cancer, FDA has not yet market approved or cleared the NanoKnife® System for use in the treatment of pancreatic cancer. The NanoKnife® System is currently being used for the treatment of Stage III pancreatic cancer in the DIRECT clinical trial in which the first patient was enrolled on May 13, 2019. Completion of the clinical trial is not expected until approximately December 2023.[424]

The applicant noted that earlier iterations of the NanoKnife® System indicated for the surgical ablation of soft tissue were available on the market after FDA clearances in 2008 and 2015. According to the applicant, NanoKnife 3.0®, the most recent iteration of the NanoKnife® System device consisting of improvements and advancements as compared to prior versions of the device, was cleared by FDA on June 19, 2019 for the surgical ablation of soft tissue and per the applicant became commercially available on the U.S. market in June 2019. Consistent with prior versions of the device, NanoKnife 3.0® is labeled for soft tissue ablation. We note that since the earlier versions of the NanoKnife® System have been available commercially on the U.S. market following FDA clearances in 2008 and 2015, these versions are not considered new. As noted previously, under the first criterion, a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. Therefore, the indication associated with the device during that timeframe, soft tissue ablation, would not be relevant for purposes of the new technology add-on payment application for FY 2021. Only the use of the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer, for which the applicant submitted its application for new technology-add on payments for FY 2021, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2021.

According to the applicant, ICD–10–PCS procedure codes 0F5G0ZF (Destruction of pancreas using irreversible electroporation, open approach), 0F5G3ZF (Destruction of pancreas using irreversible electroporation, percutaneous approach), and 0F5G4ZF (Destruction of pancreas using irreversible electroporation, percutaneous endoscopic approach) may be used to distinctly identify cases involving the NanoKnife® System because the NanoKnife® System is currently the only device used for irreversible electroporation in the United States.

The applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant used the FY 2018 MedPAR Limited Data Set (LDS) to identify the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving the NanoKnife® System would be mapped. The applicant searched for cases reporting the following predecessor ICD–10–PCS codes: 0F5G0ZZ (Destruction of pancreas, open approach), 0F5G3ZZ (Destruction of pancreas, percutaneous approach) and 0F5G4ZZ (Destruction of pancreas, percutaneous endoscopic approach). According to the applicant, this resulted in 40 cases mapped to MS–DRGs 405, 406, and 407 (Pancreas, Liver and Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). The applicant noted that cases eligible for use of the NanoKnife® System would likely map to MS–DRGs 628, 629, or 630 (Other Endocrine, Nutritional and Metabolic O.R. procedures with MCC, with CC, and without CC/MCC, respectively) as well but none of the 40 cases mapped to these MS–DRGs. However, the applicant stated that had there been cases assigned to MS–DRGs 628, 629, or 630, these would have been selected as well. The applicant also noted that cases where the open approach Whipple procedure (ICD–10–PCS code 0FBG0ZZ (Excision of pancreas, open approach)) was coded were removed, as according to the applicant it is unlikely this procedure would be performed in conjunction with IRE because the Whipple procedure is an extensive surgical

[424] *https://clinicaltrials.gov/ct2/show/study/NCT03899636?term=NanoKnife&draw=2&rank=6.*

procedure that may not be necessary with IRE. The applicant only disclosed the percentage of cases assigned to MS–DRG 406 because, according to the applicant, the number of cases assigned to MS–DRGs 405 and 407 was less than 12 for each MS–DRG, making the exact percentage for these two MS–DRGs unavailable.

The applicant examined associated charges per MS–DRG. According to the applicant, since the 40 cases mapped to MS–DRGs 405, 406 and 407 could include charges for various technologies for destruction of pancreatic tumors, and in order to exclude charges for prior technology, the applicant removed all charges billed to the medical supplies cost center for MS–DRGs 405, 406 and 407, as this cost center could include charges associated with use of various predecessor technologies for destruction of pancreatic tumors. The applicant noted it did not remove charges related to the predecessor technology as it believes that remaining charges associated with the cases would stay the same. According to the applicant, related charges consist of operating room, routine, intensive care, drug, radiology and Computed Tomography charges. The applicant then standardized the charges for each case and inflated each case's charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant then added the charges for the Nanoknife® System by dividing the costs of the device and required ancillary supplies per patient by the national average cost-to-charge ratio of 0.299 for implantable devices from the FY 2020 IPPS Final Rule (84 FR 42179). The applicant calculated a final inflated average case-weighted standardized charge per case of $175,836 and an average case-weighted threshold amount of $102,842. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion.

In the proposed rule, we agreed with the applicant that it meets the cost criterion. We also stated that, as noted previously, subject to our proposed conditional approval process for technologies for which an application is submitted under the alternative pathway for certain antimicrobial products, applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As also summarized previously, the applicant is seeking new technology-add on payments for the use of the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer, and it is only that use, and the FDA Breakthrough Device designation it received for that use, that are relevant for purposes of the new technology add-on payment application for FY 2021. Therefore, subject to the NanoKnife® System receiving FDA clearance or approval for use in the treatment of Stage III pancreatic cancer by July 1, 2020, we proposed to approve the NanoKnife® System for new technology add-on payments for FY 2021.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the NanoKnife® System is $11,086. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the NanoKnife® System would be $7,205.90 for FY 2021.

We invited public comments on whether the NanoKnife® System meets the cost criterion and our proposal to approve new technology add-on payments for the NanoKnife® System for FY 2021, subject to the NanoKnife® System receiving FDA clearance or approval for use in the treatment of Stage III pancreatic cancer by July 1, 2020.

Comment: We received a few comments expressing general support for the approval of the NanoKnife® System for new technology add-on payment for FY 2021.

We also received two comments from the applicant. (The applicant and its consultant submitted individual comments. We consider these comments to be from the applicant and on behalf of the applicant). The applicant stated, the new technology add on payment regulation applicable to medical devices that are part of FDA's Breakthrough Devices Program, 42 CFR 412.87(c)(1), has no explicit limit to the type of marketing authorization and no mandate that the marketing authorization indication be the same as Breakthrough Device Designation indication. According to the applicant, the NanoKnife® System has sufficient FDA market authorization under the broad regulatory provision in that it has a 510(k) clearance for surgical ablation of soft tissue. The applicant also stated that the NanoKnife® System has FDA Breakthrough Designation for treatment of pancreatic cancer. According to the commenter, based on the 510(k) clearance and FDA Breakthrough Designation, the NanoKnife® System should be approved for new technology add-on payment for FY 2021. Furthermore, the applicant conveyed that an FDA approved indication should reflect both regulatory and medical factors, explaining that medical authorities confirm that pancreatic cancer tissue is a form of soft tissue.[425] According to the applicant, scientific articles describe the NanoKnife® System studies including the pancreas as, ''Early Results of Irreversible Electroporation (IRE) for Tumor Ablation in Soft Tissue Tumors.'' [426] The applicant concluded that the 510(k) clearance indication covers the Breakthrough Device indication and medical facts reinforce a straightforward application of ''marketing authorization'' to recognize the overlapping the NanoKnife® System indications.

The applicant commented that even if CMS were to reject the 510(k) clearance indication, FDA has approved the NanoKnife® System's investigational device exemption (IDE) for treatment of pancreatic cancer and that in the absence of an explicit regulatory definition that limits marketing authorization to only 510(k) clearances or pre-market approvals (PMA), CMS should allow an IDE indication to satisfy the marketing authorization standard. According to the applicant, an approved IDE is an FDA authorization to; (1) advertise, promote and use the device for the indication under the clinical trial and (2) notify patients, physicians and hospitals of the availability of the device for the particular indication under the clinical trial.

According to the applicant, FDA approval of an IDE signals that the device is safe enough and offers enough potential for effectiveness to be available under the controls of the IDE. Furthermore, the applicant stated that even if limited to the clinical trial, an IDE is clearly marketing authorization and that the regulation does not exclude an IDE as market authorization. According to the applicant, if CMS

[425] National Comprehensive Cancer Network Clinical Practice Guideline Pancreatic Adenocarcinoma NCCN Evidence Blocks Version 1.2020—November 26, 2019. See for example PANC–C 2 of 2. *https://www.nccn.org/professionals/physician_gls/pdf/pancreatic_blocks.pdf.*

[426] Walsh et al. THE AMERICAN SURGEON November 2018 Vol. 84, E446. Irreversible electroporation (IRE) is NanoKnife's surgical ablation technology. See also Martin et al. *Annals of Surgery;* Volume 262, Number 3, September 2015.

wanted or looks ahead to specific types of authorizations, CMS must make those explicit in the regulation.

According to the applicant, in addition to the NanoKnife® System's 510(k) clearance and IDE, CMS has approved a number of Medicare reimbursement policies recognizing the NanoKnife® System's use for treatment of pancreatic cancer through the following:

- Approval of national Medicare coverage for treatment of pancreatic cancer under the IDE;
- Approval of ICD–10–PCS codes for treatment of the pancreas: 0F5G0ZF Destruction of pancreas using irreversible electroporation, open approach; and
- Assignment of the ICD–10–PCS codes into pancreas MS DRGs: MS DRG 405 Pancreas, liver and shunt procedures w mcc.

According to the applicant, these CMS coverage, coding and payment approvals recognizing the NanoKnife® System for pancreatic cancer, together with the 510(k) clearance and IDE indications certainly fulfill the marketing authorization new technology requirement.

Finally, the applicant asserted that there would be an inconsistency if CMS approved of national coverage under the clinical trial, allowing reimbursement for the device and the routine costs of patient care, but denied new technology add-on payment during this clinical trial. According to the applicant, the current new technology add-on payment regulation should be applied to harmonize CMS coverage, coding and payment, along with FDA policies to ensure Medicare patient access to life-saving breakthrough devices and is fully in line with the statutory authority for Breakthrough Devices under the 21st Century Cures Act. Public Law 114–255, Section 3051.

Response: We thank the applicant for their recommendations and feedback.

Regarding the applicant's comment that based on the 510(k) clearance for soft tissue ablation and FDA Breakthrough Device designation for treatment of Stage III pancreatic cancer, the NanoKnife® System should be approved for new technology add-on payment for FY 2021 under the alternative pathway for certain transformative devices, we disagree. As discussed in response to comments in section II.G.8, we believe the applicant is asking CMS to evaluate this technology inconsistent with longstanding policy and to start the newness period prior to the time a product receives marketing authorization. As discussed in the proposed rule and elsewhere in this final rule, in the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46915), we indicated that an existing technology can receive new technology add on payments for a new use or indication. As we stated in the proposed rule, while we recognize that a technology can have multiple indications, each indication has its own newness period and must meet the new technology add on payment criteria. The applicable criteria will depend on whether the technology is eligible for an alternative new technology add-on payment pathway. However, each indication for the technology is evaluated separately from any other indication, including with respect to the start of the newness period, to determine whether the technology is eligible for new technology add-on payments when used for that indication. CMS did not modify this longstanding policy for evaluating whether a technology with multiple indications has received the required marketing authorization when it adopted the alternative pathway for certain transformative new devices in FY 2020.

Regarding the applicant's comment that the 510(k) clearance indication for soft tissue covers the Breakthrough Device designation indication for treatment of Stage III pancreatic cancer and that the medical facts reinforce a straightforward application of ''marketing authorization'' to recognize the overlapping the NanoKnife® System indications should result in the approval of the NanoKnife® System for FY 2021 under the alternative pathway for certain transformative devices, we also disagree. First, as previously discussed, each indication for the technology is evaluated separately from any other indication, including with respect to the start of the newness period, to determine whether the technology is eligible for new technology add-on payments when used for that indication. Also as explained previously, and in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Therefore, as discussed in the proposed rule, since the earlier versions of the NanoKnife® System, indicated for soft tissue ablation, have been available commercially on the U.S. market following FDA clearances in 2008 and 2015 and are not considered new, the 510(k) clearance indication for soft tissue ablation would not be relevant for purposes of the new technology add-on payment application for FY 2021. Also as discussed in the proposed rule, only the indication with six outputs for the treatment of Stage III pancreatic cancer is relevant for purposes of the new technology add-on payment application for FY 2021 under the alternative pathway for certain transformative devices. We refer readers to our response to comments in section II.G.8 of the preamble of this final rule for further discussion of these existing policies.

Regarding the suggestion that an IDE can qualify as marketing authorization and that the IDE determination can match the Breakthrough Designation indication for new technology add-on payment eligibility, we disagree. It is our understanding that an IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data prior to the device receiving FDA marketing authorization (that is, received PMA approval, 510(k) clearance, or the granting of De Novo classification request). Therefore, we do not believe that an IDE qualifies as marketing authorization.[427]

For these same reasons, we disagree that any separate policies relating to coverage, coding and payment, combined with the 510(k) clearance for the separate indication of soft tissue ablation and IDE indication for treatment of Stage III pancreatic cancer, should allow for the approval of new technology add-on payments for the NanoKnife® System for FY 2021 when used for treatment of Stage III pancreatic cancer. Regarding the comments about national coverage determinations, payment and coding, we note that the new technology add-on payment policy is separate and distinct from the specific processes for coverage, coding, and payment. As discussed previously, those with further questions about Medicare's coverage, coding, and payment processes, or those who want further guidance about how they can navigate these processes, can contact The Council on Technology and Innovation (CTI) at *CTI@cms.hhs.gov*.

Therefore, for the reasons stated in the proposed rule and in this final rule, because the NanoKnife® System did not receive FDA clearance or approval by July 1, 2020 for use in the treatment of

[427] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide.*

Stage III pancreatic cancer, which is the indication for which it received FDA Breakthrough Device Designation and for which it applied for new technology add-on payments for FY 2021, we are not approving new technology add-on payments for the NanoKnife® System for FY 2021. The applicant for the NanoKnife® System would remain eligible to apply for the new technology add on payment under the alternative pathway for certain transformative new devices for a future fiscal year.

(3) Optimizer System

Impulse Dynamics submitted an application for The Optimizer® System (QFV). The Optimizer® System is intended for the treatment of chronic heart failure in patients with advanced symptoms that have normal QRS duration and are not indicated for cardiac resynchronization therapy.

Per the applicant, the Optimizer System consists of three components. First, the Optimizer Rechargeable Implantable Pulse Generator (IPG) is designed for subcutaneous implant and delivers cardiac contractility modulation to the heart via two standard pacing leads attached to the right ventricular septum. Second, the Optimizer Mini Charger recharges the Optimizer IPG. Finally, the Omni II Programmer with Omni SMART Software gives a qualified healthcare professional the ability to program the Optimizer IPG over a large range of clinical settings.

The applicant explained that the Optimizer IPG is implanted in the right pre-pectoral region, similar to cardiac rhythm management devices. According to the applicant, the procedure is performed in a cardiac catheterization laboratory under fluoroscopic guidance with the patient under light sedation. The applicant stated that since three intracardiac leads are used, subclavian venous access is preferred over access via the axillary or cephalic vein. The applicant stated that the Optimizer IPG is connected to the heart via two standard implantable pacing leads that are each placed into the right ventricular septum.

With respect to the newness criterion, the applicant indicated that FDA granted Breakthrough Device designation for the Optimizer System on March 21, 2019. The applicant received FDA premarket approval for the two-lead Optimizer System, which included placement of the two leads in the right ventricular septum, on October 23, 2019. The device was available in the market immediately following FDA approval.

The applicant asserted that the current ICD–10–PCS codes 0JH60AZ (Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach), 0JH63AZ (Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach), 0JH80AZ (Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach) and 0JH83AZ (Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach) identify the Optimizer System.

With regard to the cost criterion, the applicant conducted an analysis using the FY 2018 MedPAR Limited Data Set (LDS) to demonstrate that the Optimizer System meets the cost criterion.

The applicant first searched the FY 2018 MedPAR data for cases reporting the procedure codes listed in this section to identify potential cases representing hospitalized patients who may be eligible for treatment using the Optimizer® System. The applicant limited its search to MS–DRG 245 (AICD Generator Procedures), which it asserts is the typical MS–DRG assignment for implanting a contractility modulation device. The applicant identified 2,049 cases that met the criterion of having at least one of the following relevant ICD–10–PCS procedure codes:

ICD-10-PCS Procedure Codes Describing a Contract Modulation Device Implant	
ICD-10-PCS Code	**ICD-10-PCS Description**
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
0JH83AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach

ICD-10-PCS Procedure Codes Describing Insertion of Leads	
ICD-10-PCS Code	**ICD-10-PCS Description**
02HK0MZ	Insertion of cardiac lead into right ventricle, open approach
02HK3MZ	Insertion of cardiac lead into right ventricle, percutaneous approach
02H60MZ	Insertion of cardiac lead into right atrium, open approach
02H63MZ	Insertion of cardiac lead into right atrium, percutaneous approach

The applicant determined an average unstandardized charge per case of $180,319. The applicant then removed all charges for prior technology by removing charges associated with the service categories Prosthetic/Orthotic (revenue center 0274), Pacemakers (revenue center 0275) and other implantables (revenue center 0278), as the applicant believed the Optimizer® System will typically not be implanted concomitantly with other devices during the hospital admission. The applicant then standardized the charges and applied the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629) to update the charges from FY 2018 to FY 2020.

The applicant added the charges for the new technology by dividing its cost per patient by the national average cost-to-charge ratio of 0.299 for implantable devices from the FY2020 IPPS Final Rule (84 FR 42179).

The applicant calculated a final inflated average case-weighted standardized charge per case of $190,167, which it stated exceeded the average case-weighted threshold amount of $148,002 by $42,165.

The applicant also conducted a subsequent analysis that only included patients with a diagnosis of heart failure. The applicant once again limited its search to MS–DRG 245 and refined its sample by including only cases with one of the ICD–10–PCS

procedure codes listed previously and an ICD–10–CM diagnosis code from Category I50 (Heart Failure) on the claim. This resulted in 1,698 cases with an average unstandardized charge per case of $183,243. After following the same order of operations as the first analysis, the final inflated average case weighted standardized charge per case was $192,237, which exceeded the average case weighted threshold amount of $148,002. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both analyses described previously, the applicant maintains that the technology meets the cost criterion.

In the proposed rule, we stated that we agree with the applicant that the technology meets the cost criterion and therefore proposed to approve the Optimizer® System for new technology add-on payments for FY 2021. As previously noted, the applicant asserted that ICD–10–PCS codes 0JH60AZ, 0JH63AZ, 0JH80AZ and 0JH83AZ identify the Optimizer® System.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of the Optimizer® System is $23,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the Optimizer® System would be $14,950 for FY 2021.

We invited public comments on whether the Optimizer® System meets the cost criterion and our proposal to approve new technology add-on payments for the Optimizer® System for FY 2021.

Comment: Commenters supported CMS' intent to improve beneficiary's access to new technology and supported CMS' proposal to approve new technology add-on payments for FY 2021 for Optimizer® System.

Response: We appreciate the commenters' support.

Based on the information provided in the applicant's new technology add-on payment application and after consideration of the public comments we received, we believe that Optimizer® System meets the cost criterion. The Optimizer® System received marketing authorization from the FDA on October 23, 2019 for the indication covered by its Breakthrough Device designation.

Therefore, we are finalizing our proposal to approve new technology add-on payments for Optimizer® System for FY 2021, and we consider the newness period to commence on October 23, 2019 when the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. Under § 412.88(a)(2)(ii)(A), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing a maximum new technology add-on payment of $14,950 for a case involving the use of the Optimizer® System for FY 2021(that is 65 percent of the average cost of the technology). Cases involving the use of Optimizer® System that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes 0JH60AZ, 0JH63AZ, 0JH80AZ or 0JH83AZ.

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) Cefiderocol (Fetroja)

Shionogi & Co. Ltd (Company) submitted an application for Cefiderocol (Fetroja), a β-lactam antibiotic indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible Gram-negative (GN) pathogens: *Escherichia coli* (including with concurrent bacteremia), *Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Citrobacter freundii, Enterobacter cloacae, Morganella morganii,* and *Serratia marcescens.* Per the applicant, Cefiderocol should be used to treat infections where limited or no alternative treatment options are available and where cefiderocol is likely to be an appropriate treatment option, which may include use in patients with infections caused by documented or highly suspected carbapenem-resistant (CR) and/or multidrug-resistant GN pathogens.

The applicant describes Cefiderocol as an injectable siderophore cephalosporin. The applicant asserts that the principal antibacterial/bactericidal activity of Cefiderocol occurs with inhibiting GN bacterial cell wall synthesis by binding to penicillin-binding proteins. The applicant contends that Cefiderocol is unique in that it can enter the bacterial periplasmic space (in addition to the typical entry point via porin channels) as a result of its siderophore-like property, has enhanced stability to β-lactamases, and has activity limited to GN aerobic bacteria only.

Per the applicant, cUTIs are the second leading cause of hospitalization in the elderly and have substantial morbidity and worse outcomes if the causative pathogens are carbapenem-resistant (CR). According to the applicant, bloodstream infection (BSI) is often associated with cUTI, known as urosepsis, with an associated mortality rate of 9 to 31 percent. The applicant asserts that patients who develop cUTI due to a CR pathogen are at greater risk for prolonged hospital stays and progression to a BSI or urosepsis. The applicant stated that CR is a growing problem in the US and around the world, with increasing infections due to strains that are resistant to most or all currently available antibiotics. The applicant further states that, compared to susceptible pathogens, CR pathogens cause prolonged hospital and intensive care unit (ICU) stays, worse discharge status, and greater mortality.

Cefiderocol is designated as a QIDP and received FDA approval on November 19, 2019. However, according to the applicant, Cefiderocol was not commercially available until February 24, 2020 due to the finalization of the materials associated with the commercial launch of a drug, which could not be completed until the final label with FDA was determined. The applicant submitted a request for approval of unique ICD 10 PCS procedure codes for the administration of Cefiderocol beginning in FY 2021 and was granted approval for the following procedure codes effective October 1, 2020: XW03366 or XW04366.

With regard to the cost criterion, the applicant conducted two analyses based on 100% and 75% of identified claims. For both scenarios, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for Cefiderocol treatment would be mapped. The applicant identified eligible cases by searching the FY 2018 MedPAR for cases reporting one of the following ICD–10–CM codes:

ICD-10-CM Code	Description
K68.11	Postprocedural retroperitoneal abscess
N10	Acute pyelonephritis
N11.1	Chronic obstructive pyelonephritis
N12	Tubulo-interstitial nephritis, not specified as acute or chronic
N13.6	Pyonephrosis
N15.1	Renal and perinephric abscess
N28.84	Pyelitis cystica
N28.85	Pyeloureteritis cystica
N30.00	Acute cystitis without hematuria
N30.01	Acute cystitis with hematuria
N30.80	Other cystitis without hematuria
N30.81	Other cystitis with hematuria
N30.90	Cystitis, unspecified without hematuria
N39.0	Urinary tract infection, site not specified
N41.0	Acute prostatitis
N99.521	Infection of incontinent external stoma of urinary tract
O03.38	Urinary tract infection following incomplete spontaneous abortion
O03.88	Urinary tract infection following complete or unspecified spontaneous abortion
O04.88	Urinary tract infection following (induced) termination of pregnancy
O07.38	Urinary tract infection following failed attempted termination of pregnancy
O08.83	Urinary tract infection following an ectopic and molar pregnancy
O23.02	Infections of kidney in pregnancy, second trimester
O23.03	Infections of kidney in pregnancy, third trimester
O23.30	Infections of other parts of urinary tract in pregnancy, unspecified trimester
O23.40	Unspecified infection of urinary tract in pregnancy, unspecified trimester
O23.41	Unspecified infection of urinary tract in pregnancy, first trimester
O23.42	Unspecified infection of urinary tract in pregnancy, second trimester
O23.43	Unspecified infection of urinary tract in pregnancy, third trimester
O86.20	Urinary tract infection following delivery, unspecified
O86.21	Infection of kidney following delivery
O86.29	Other urinary tract infection following delivery
T81.4XXA	Infection following a procedure, initial encounter
T83.511A	Infection and inflammatory reaction due to indwelling urethral catheter, initial encounter
T83.512A	Infection and inflammatory reaction due to nephrostomy catheter, initial encounter
T83.518A	Infection and inflammatory reaction due to other urinary catheter, initial encounter
T83.590A	Infection and inflammatory reaction due to implanted urinary neurostimulation device, initial encounter
T83.591A	Infection and inflammatory reaction due to implanted urinary sphincter initial encounter
T83.592A	Infection and inflammatory reaction due to implanted indwelling ureteral stent initial encounter
T83.593A	Infection and inflammatory reaction due to other urinary stents, initial encounter
T83.598A	Infection and inflammatory reaction due to other prosthetic device, implant and graft in urinary system, initial encounter
T83.59XA	Infection and inflammatory reaction due to prosthetic device, implant and graft in urinary system, initial encounter
T83.61XA	Infection and inflammatory reaction due to other prosthetic device, due to implanted penile prosthesis, initial encounter
T83.62XA	Infection and inflammatory reaction due to other prosthetic device, due to implanted testicular prosthesis, initial encounter
T83.69XA	Infection and inflammatory reaction due to other prosthetic device, implant and graft in genital track, initial encounter
T86.13	Kidney transplant infection

Under the first scenario of 100 percent of cases, the applicant identified 1,461,784 cases mapping to 656 MS–DRGs. Under the second scenario of 75 percent of cases, the applicant identified 1,097,594 cases mapping to 53 MS–DRGs. The applicant standardized the charges after calculating the average case-weighted unstandardized charge per case for both scenarios and removing 50 percent of charges associated with the drug revenue centers 025x, 026x, and 063x under both scenarios. (Per the applicant, Cefiderocol is expected to replace some of the drugs that would otherwise be utilized to treat these patients. The applicant stated that it believes 50 percent of these total charges to be a conservative estimate as other drugs will still be required for these patients during their hospital stay.) The applicant then applied an inflation factor of 11.1 percent, which was the two-year outlier charge inflation factor used in the FY 2020 IPPS/LTCH PPS final rule, to update the charges from FY 2018 to FY 2020. The applicant then added charges for Cefiderocol by dividing the total average hospital cost of Cefiderocol by the national average cost-to-charge ratio (0.189) for drugs published in the FY 2020 IPPS/LTCH PPS final rule.

The applicant calculated a final inflated average case-weighted standardized charge per case of $116,131 for the first scenario and $106,037 for the second scenario and an average case-weighted threshold amount of $55,885 for the first scenario and $50,887 for the second scenario.

Because the final inflated average case-weighted standardized charge per case for each scenario exceeds the average case-weighted threshold amount for each scenario, the applicant asserted that the technology meets the cost criterion.

In the proposed rule we stated that we agree with the applicant that Cefiderocol meets the cost criterion and therefore proposed to approve Cefiderocol for new technology add-on payments for FY 2021. As previously noted, the applicant has received unique ICD–10–PCS procedure codes to identify cases involving the administration of Cefiderocol.

In its application, the applicant stated that the cost of Cefiderocol is $10,559.81. Under 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving the administration of Cefiderocol would be $7,919.86 for FY 2021 (that is 75 percent of the average cost of the technology).

We invited public comments on whether Cefiderocol meets the cost criterion and our proposal to approve new technology add-on payments for Cefiderocol for FY 2021.

Comment: Several commenters, including the applicant, supported CMS' proposal to approve new technology add-on payments for FY 2021 for Cefiderocol Infusion. The applicant also further confirmed CMS' methodology of arriving at the maximum new technology add-on payment as stated in the FY 2021 proposed rule for Cefiderocol as appropriate.

Response: We appreciate the commenters' support.

Based on the information provided in the applicant's new technology add-on payment application and after consideration of the public comments we received, we believe that Cefiderocol meets the cost criterion. As previously discussed, Cefiderocol received FDA approval on November 19, 2019 for use in the treatment of (cUTI) but was not commercially available until February 24, 2020. Therefore, we are finalizing our proposal to approve new technology add-on payments for Cefiderocol for FY 2021, and we consider the beginning of the newness period to commence when the technology became commercially available on February 24, 2020. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the amount by which the costs of the case exceed the standard MS–DRG payment. As a result, we are finalizing a maximum new technology add-on payment of $7,919.86 for a case involving the use of Cefiderocol for FY 2021(that is 75 percent of the average cost of the technology). Cases involving the use of Cefiderocol that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW03366 or XW04366.

(2) Contepo

CONTEPO™ (fosfomycin for injection), is intended for treatment of complicated urinary tract infections (cUTI) and is designated by FDA as a QIDP. In October 2018, Nabriva Therapeutics submitted a New Drug Application (NDA) to the US–FDA seeking marketing approval of IV fosfomycin for injection (ZTI–01) for the treatment of patients 18 years and older with cUTI including acute pyelonephritis (AP) caused by designated susceptible bacteria. The applicant noted that once approved, CONTEPO will represent the first FDA-approved IV epoxide antibiotic in the United States.

On April 30, 2019, Nabriva received a Complete Response Letter (CRL) from FDA for the NDA seeking marketing approval of CONTEPO (fosfomycin) for injection. The applicant stated that the CRL from FDA requests that Nabriva address issues related to facility inspections and manufacturing deficiencies at one of Nabriva's contract manufacturers prior to FDA approving the NDA. Nabriva had resubmitted its NDA to FDA with FDA setting a Prescription Drug User Fee Act (PDUFA) goal date of June 19, 2020 for the completion of its review of the NDA.

The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™ in 2019. Effective October 1, 2019, CONTEPO™ administration can be identified by ICD–10–PCS procedure codes XW033K5, (Introduction of Fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) and XW043K5 (Introduction of Fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5), which the applicant states are unique to CONTEPO administration.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving CONTEPO™ would most likely be mapped. According to the applicant, CONTEPO™ is anticipated to be indicated for the treatment of hospitalized patients who have been diagnosed with complicated urinary tract infections (cUTIs). The applicant identified 199 ICD–10–CM diagnosis code combinations that identify hospitalized patients who have been diagnosed with a cUTI. Searching the FY 2018 MedPAR data file for these ICD–10–CM diagnosis codes resulted in a total of 684,664 potential cases that span 570 unique MS–DRGs, 522 of which contained more than 10 cases. The applicant excluded MS–DRGs with minimal volume (that is, 10 cases or less) from the cohort of the analysis (a total of 252 cases and 48 MS–DRGs), and this resulted in a total of 684,412 cases across 522 MS–DRGs.

The applicant examined associated charges per MS–DRG and removed charges for potential antibiotics that may be replaced by the use of CONTEPO™. Specifically, the applicant identified 5 antibiotics currently used for the treatment of patients who have been diagnosed with a cUTI and calculated the cost of each of these drugs for administration over 14 day inpatient hospitalization. Because patients who have been diagnosed with a cUTI would typically only be treated with one of these antibiotics at a time, the applicant estimated an average of the 14-day cost for the 5 antibiotics. The applicant then converted the cost to charges by dividing the costs by the national average CCR of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179).

The applicant then standardized the charges for each case and inflated each case's charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant then added the charges for the new technology by calculating the per-day cost per patient. The applicant noted that the duration of therapy of up to 14 days (patients that had a cUTI with concurrent bacteremia) is consistent with the prospective prescribing information, and that it used this 14-day duration of therapy to calculate total inpatient cost. The applicant then converted these costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). The applicant calculated a final inflated average case-weighted standardized charge per case of $75,533 and a case weighted threshold of

$55,447. Because the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant maintained it meets the cost criterion.

As summarized, the applicant used a 14-day duration of therapy to calculate total inpatient cost for purposes of its cost analysis. However, the applicant noted that the average number of days a patient would be administered CONTEPO™ will most likely fall between 10–14 days of therapy given the current guideline recommendations. Of these treatment days, the applicant noted that nearly all would occur during the inpatient hospital stay. Consistent with our historical practice, we stated in the proposed rule that we believe the new technology add-on payment for CONTEPO™, if approved, would be based on the average cost of the technology and not the maximum. For example, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53358), we approved new technology add-on payments for DIFICID™ based on the average dosage of 6.2 days rather than the maximum 10 day dosage. Without further information from the applicant regarding the average number of days CONTEPO™ is administered, we stated that we believe using the middle ground of 12.5 days, based on the 10–14 day period indicated by the applicant, is appropriate for this analysis to determine the average number of days CONTEPO™ is administered in the hospital. To assess whether the technology would meet the cost criterion using an average cost for the technology based on this 12.5-day period for CONTEPO™ administration, we converted the costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). Based on data from the applicant, this resulted in a final inflated average case-weighted standardized charge per case of $73,548 which exceeds the case weighted threshold of $55,447.

Because of the large number of cases included in this cost analysis, the applicant supplemented the analysis as described previously with additional sensitivity analyses. In these analyses, the previous cost analysis was repeated using only the top 75 percent of cases, the top 20 MS–DRGs, and the top 10 MS–DRGs. In these three additional sensitivity analyses, the final inflated average case-weighted standardized charge per case for CONTEPO™ of $64,019, $62,486 and $61,158 exceeded the average case-weighted threshold amount of $51,085, $50,704 and $49,889, respectively. We note that the applicant did not use the thresholds from the correction notice to case weight the charges, however the variance is minimal with the final inflated average case-weighted standardized charge per case well in excess of the case weighted threshold amounts. Because the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant asserts that CONTEPO™ meets the cost criterion.

In the proposed rule, we stated that we believe that CONTEPO™ meets the cost criterion and therefore proposed to approve CONTEPO™ for new technology add-on payments for FY 2021. As previously noted, the applicant has received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™.

As discussed previously, we stated in the proposed rule that without further information from the applicant regarding the average number of days CONTEPO™ is administered, we believe using a 12.5 day duration of therapy is a reasonable approach for estimating the average cost of the technology. Based on preliminary information from the applicant at the time of the proposed rule, the cost of CONTEPO™ administered over 12.5 days is $3,125. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving the administration of CONTEPO™ would be $2,343.75 for FY 2021 (that is 75 percent of the average cost of the technology).

We invited public comments on whether CONTEPO™ meets the cost criterion and our proposal to approve new technology add-on payments for CONTEPO™ for FY 2021.

Comment: Several commenters supported CMS' proposal to approve new technology add-on payments for FY 2021 for CONTEPO™ infusion.

Response: We appreciate the commenters' support.

Comment: A commenter, the applicant, supported CMS' proposal to approve new technology add-on payments for FY 2021 for CONTEPO™ and notified CMS that the applicant plans to request a Type A meeting with FDA to discuss appropriate next steps and FDA's plans for completing foreign facility inspections. The applicant stated that it will inform CMS on the status of the CONTEPO NDA once the application is resubmitted and a new PDUFA date is confirmed. The applicant also agrees with CMS of using 12.5-day duration of therapy for estimating the average cost of the technology. The applicant further agrees that using the thresholds from the FY 2020 final rule as opposed to the correction notice to case weight the charges for CONTEPO™ has no impact on meeting the cost criterion (final inflated average case-weighted standardized charges per case are well in excess of the case weighted threshold).

Response: We appreciate the applicant's comments. We agree that CONTEPO™ meets the cost criterion.

As discussed later in this section of this rule, we are finalizing our proposal to provide for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the later discussion in this section of this rule for complete details regarding this final policy. Therefore, because CONTEPO™ otherwise meets the new technology add-on payment criteria under the alternative pathway for products designated as QIDPs, we are granting a conditional approval for CONTEPO™ for new technology add-on payments, subject to the technology receiving FDA marketing authorization by July 1, 2021 (that is, by July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2021)). If CONTEPO™ receives FDA marketing authorization before July 1, 2021, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If the FDA marketing authorization is received on or after July 1, 2021, no new technology add-on payments will be made for cases involving the use of CONTEPO™ for FY 2021.

After consideration of the comments received, we are also finalizing our proposal to use a 12.5 day duration of therapy to estimate the average cost of the technology. Under § 412.88(a)(2)(ii)(B), we limit new

technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the amount by which the costs of the case exceed the standard MS–DRG payment. If CONTEPO™ receives FDA approval prior to July 1, 2021, the maximum new technology add-on payment for a case involving the administration of CONTEPO™ is $2,343.75 for FY 2021 (that is 75 percent of the average cost of the technology). Cases involving the use of CONTEPO™ that would be eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033K5, (Introduction of Fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043K5 (Introduction of Fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5).

(3) NUZYRA® for Injection

Paratek Pharmaceuticals submitted an application for new technology add-on payments for NUZYRA® (omadacycline) for Injection for FY 2021. According to the applicant, NUZYRA® for Injection is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.
- Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: Staphylococcus aureus (methicillin susceptible and resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae.

The applicant explained that NUZYRA® for Injection is supplied as a lyophilized powder in a single-dose colorless glass vial, with each vial containing 100 mg of NUZYRA® (equivalent to 131 mg omadacycline tosylate). 100-mg single dose vials are packaged in cartons of 10. The NDC number is 71715–001–02. Additionally, the applicant noted that while an oral formulation of NUZYRA® is available, NUZYRA® can also be administered through intravenous infusion. Providers may determine which method of administration is clinically appropriate for each patient. Adult patients with CABP must receive their initial loading dose of NUZYRA® via intravenous infusion. The applicant specified that NUZYRA® for Injection should not be administered with any solution containing multivalent cations, for example, calcium and magnesium, through the same intravenous line. Co-infusion with other medications has not been studied. The applicant conveyed that for treatment of adults with CABP, the recommended dosage regimen of NUZYRA® for Injection is as follows (Use NUZYRA for injection administered by intravenous infusion for the loading dose in CABP patients):

Loading Dose	Maintenance Dose	Treatment Duration
200-mg by intravenous infusion over 60 minutes on the first day.	100-mg by intravenous infusion once daily infused over 30 minutes.	7 to 14 days

For treatment of adults with ABSSSI, the recommended dosage regimen of NUZYRA® for injection is as follows (Use NUZYRA® for injection administered by intravenous infusion or NUZYRA® tablets orally administered for the loading dose in ABSSSI patients):

Loading Dose	Maintenance Dose	Treatment Duration
200-mg by intravenous infusion over 60 minutes on the first day.	100-mg by intravenous infusion once daily infused over 30 minutes.	7 to 14 days

Finally, the applicant indicated that no dose adjustment is warranted in patients with renal or hepatic impairment.

According to the applicant, NUZYRA® for Injection was submitted for FDA approval under a New Drug Application (identified as NDA 209817). After Fast Track and Priority Review consideration, NUZYRA® for Injection received FDA approval on October 2, 2018. According to information provided by the applicant, NUZYRA® for Injection was designated as a QIDP and granted priority review. According to the applicant, NUZYRA® for Injection became commercially available in February 2019. The applicant explained that the delay in commercial availability was due to an effort to prepare the distribution and supply channel (pharmacies and wholesalers) and to prepare for a full promotional launch.

The applicant submitted a request for approval of unique ICD–10–PCS procedure codes for the administration of NUZYRA® for Injection beginning in FY 2021 and was granted approval for the following ICD–10–PCS procedure codes effective October 1, 2020: XW033B6 (Introduction of omadacycline anti-infective into peripheral vein, percutaneous approach, new technology group 6) or XW043B6 (Introduction of omadacycline anti-infective into peripheral vein, percutaneous approach, new technology group 6).

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to identify potential cases that may be eligible for treatment involving NUZYRA® for Injection. To ensure appropriate discharges were used from the dataset, the following edits were made:

- Claims paid by a Managed Care Organization were removed.
- Duplicated records with the same beneficiary ID, provider, admission data, and discharge date were removed.

- Interim claims were combined into discharge records.
- Discharges with covered charges of zero dollars and discharges with zero covered days were removed.
- Discharges from IPPS hospitals, as determined by the FY 2020 IPPS Impact File and discharges with discharge dates from October 1, 2017 to September 30, 2018 were included.
- Statistical outliers with standard charges that were outside of the range of +/− 3 standard deviations from the geometric mean standardized charge by MS–DRG were removed.

After these edits were made, the applicant selected discharges that had a primary or secondary diagnosis for ABSSSI or CABP, using a wide list of ICD–10–PCS codes, which resulted in a total of 1,745,649 discharges. Using these 1,745,649 discharges, 37 MS–DRGs were selected based on one of the following criteria:

- MS–DRGs with the highest volume of discharges with a primary or secondary diagnosis for ABSSSI or CABP (which represent 70 percent of all discharges with ABSSSI or CABP).
- MS–DRGs with at least two-thirds of discharges with a primary or secondary diagnosis of ABSSSI or CABP.

Using this method, the applicant identified 1,226,429 total cases which mapped to the following 37 unique MS–DRGs:

MS-DRG	DESCRIPTION
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
166	Other Respiratory System O.R. Procedures with MCC
177	Respiratory Infections and Inflammations with MCC
178	Respiratory Infections and Inflammations with CC
189	Pulmonary Edema and Respiratory Failure
190	Chronic Obstructive Pulmonary Disease with MCC
193	Simple Pneumonia and Pleurisy with MCC
194	Simple Pneumonia and Pleurisy with CC
195	Simple Pneumonia and Pleurisy without CC/MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
280	Acute Myocardial Infarction, Discharged Alive with MCC
291	Heart Failure and Shock with MCC
308	Cardiac Arrhythmia and Conduction Disorders with MCC
314	Other Circulatory System Diagnoses with MCC
377	G.I. Hemorrhage with MCC
571	Skin Debridement with CC
572	Skin Debridement without CC/MCC
574	Skin Graft For Skin Ulcer or Cellulitis with CC
580	Other Skin, Subcutaneous Tissue and Breast Procedures with CC
602	Cellulitis with MCC
603	Cellulitis without MCC
616	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC
617	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC
623	Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with CC
638	Diabetes with CC
682	Renal Failure with MCC
683	Renal Failure with CC
689	Kidney and Urinary Tract Infections with MCC
690	Kidney and Urinary Tract Infections without MCC
698	Other Kidney and Urinary Tract Diagnoses with MCC
853	Infectious and Parasitic Diseases with O.R. Procedure with MCC
854	Infectious and Parasitic Diseases with O.R. Procedure with CC
857	Postoperative or Post-Traumatic Infections with O.R. Procedure with CC
863	Postoperative and Post-Traumatic Infections without MCC
870	Septicemia or Severe Sepsis with MV >96 Hours
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
872	Septicemia or Severe Sepsis without MV >96 Hours without MCC

Next, using the cases mapping to these selected MS–DRGs, the applicant removed pharmacy charges for other drugs and standardized the charges. Then, the applicant inflated the standardized charges from FY 2018 to FY 2020 using a 2-year charge inflation factor of 11.1 percent, based on the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629).

The applicant estimated the cost of NUZYRA® for Injection based on an average inpatient stay of 5 days in the clinical trial.[428] Some patients may be required to stay longer than 5 days, resulting in increased charges. Using a loading dose for day 1 and maintenance doses in days 2 through 5 results in use of 6 vials. Each vial costs $345, resulting in a total cost for the new technology of $2,070. The applicant estimated charges for the drug by dividing the cost by the national average cost-to-charge (CCR) for drugs of 0.189, as set forth in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). This resulted in estimated charges of $10,952. The applicant then added $10,952 of charges for the drug which resulted in a final inflated average case-weighted standardized charge per case of $58,922. The applicant determined an average case-weighted threshold amount of $53,899. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion.

In the proposed rule we stated that we agreed with the applicant that it meets the cost criterion and therefore proposed to approve NUZYRA® for Injection for new technology add-on payments for FY 2021. As previously noted, the applicant has received unique ICD–10–PCS procedure codes to identify cases involving the administration of NUZYRA® for Injection.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of NUZYRA® for Injection is $2,070. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of NUZYRA® for Injection would be $1,552.50 for FY 2021 (that is 75 percent of the average cost of the technology).

We invited public comments on whether NUZYRA® for Injection meets the cost criterion and our proposal to approve new technology add-on payments for NUZYRA® for Injection for FY 2021.

Comment: A commenter supported CMS' proposal to approve new technology add-on payments for FY 2021 for NUZYRA® for Injection.

Response: We appreciate the commenter's support.

Based on the information included in the applicant's new technology add-on payment application and after consideration of the public comments we received, we believe that NUZYRA® for Injection meets the cost criterion. As previously discussed, NUZRYRA for Injenction received FDA approval on October 2, 2018, but was not commercially available until February 1, 2019. Therefore, we are finalizing our proposal to approve new technology add-on payments for NUZRYA for Injection for FY 2021, and we consider the beginning of the newness period to commence when the technology became commercially available on February 1, 2019. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the amount by which the costs of the case exceed the standard MS–DRG payment. Therefore, we are finalizing a maximum new technology add-on payment of $1,552.50 for a case involving the use of NUZYRA® for Injection for FY 2021(that is 75 percent of the average cost of the technology). Cases involving the use of NUZYRA® for Injection that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033B6 or XW043B6.

(4) RECARBRIO™

Merck submitted an application for new technology add-on payments for RECARBRIO™ for FY 2021. RECARBRIO™ is a fixed-dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel β-lactamase inhibitor (BLI). According to the applicant, RECARBRIO™ is intended for the treatment of complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) for patients 18 years of age and older. RECARBRIO™ is administered via intravenous infusion.

The applicant explained that the recommended dose of RECARBRIO™ is 1.25 grams administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CLcr) 90 mL/min or greater. According to the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose and 4 doses per day. Per RECARBRIO™'s prescribing information, the recommended duration of treatment with RECARBRIO™ is 4 days to 14 days.

According to information provided by the applicant, RECARBRIO™ is designated by FDA as a QIDP and received FDA approval on July 16, 2019 for injection in patients 18 years of age and older who have limited or no alternative treatment options for the treatment of the following infections caused by certain susceptible gram-negative bacteria: cUTI including pyelonephritis and cIAI. According to the applicant, RECARBRIO™ became commercially available on the U.S. market on January 6, 2020. The applicant stated that the delay in commercial availability was due to manufacturing considerations. According to the applicant, RECARBRIO™ can be identified with ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam antiinfective-into central vein, percutaneous approach, new technology group 5).

To demonstrate that the technology meets the cost criterion, the applicant searched the FY 2018 MedPAR Limited Data Set (LDS) for cases reporting ICD–10–CM diagnosis codes for either cUTI or cIAI with ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5 or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5) to identify the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving RECARBRIO™ would be mapped. The applicant identified a total 25,379 cases which were mapped to 453 unique MS–DRGs. There were 299 MS–DRGs with minimal frequencies (fewer than 11 cases), with a total of 1,140 cases associated with such low-volume MS–DRGs. After excluding the cases that were mapped to these low-volume MS–DRGs, the applicant identified 24,239 cases that were mapped to 153 unique MS–DRGs. The applicant examined associated charges per MS–DRG and

[428] Doe, et al., ''Reducing mortality in disease X population: Analysis,'' *JAMA* 2019, vol. 2(5), pp. 12–23.

removed all pharmacy charges that will be replaced through the use of RECARBRIO™. The applicant standardized the charges and inflated the charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant estimated an average cost of RECARBRIO™ for the treatment of cUTI or cIAI in the inpatient setting based on the recommended dose of 1.25 grams (imipenem 500 mg, cilastatin 500 mg, relebactam 250 mg) administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CLcr) 90 mL/min or greater. As previously stated, according to the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose, 4 doses per day within a recommended treatment duration of 4 to 14 days. To determine the cost per patient, the applicant stated it used the FY 2018 MedPAR analysis of total cases representing hospitalized patients who may be eligible for treatment involving RECARBRIO™ to identify a percentage of total cases per indication: cUTI equaled 88.6 percent of cases and cIAI equaled 11.4 percent. According to the applicant, it next identified the average length of stay per indication: cUTI 6.4 days and cIAI 9.7 days. According to the applicant, it also assumed that 70 percent of patients would receive RECARBRIO™ beginning on the fourth day after admission while the remaining 30 percent of these patients would receive RECARBRIO™ beginning on the second day of their hospitalization. According to the applicant, it multiplied the daily dose cost by the two scenarios for each cUTI and cIAI indication to determine the cost per stay for each indication by days of drug use. According to the applicant, next it multiplied the cost per stay for each indication by the share of cases by days in use (70/30 percent split) to determine the weighted cost for days in use estimation. According to the applicant, it summed the 70/30 percent case breakdown (weighted cost) for patients initiating on day 2 and 4 to determine the average cost per indication for cUTI and cIAI. Finally, according to the applicant, it multiplied the average cost per indication by the percent of total cases for cUTI and cIAI, then summed them to get the overall average cost. The applicant converted this cost to a charge by dividing the costs by the national average cost-to-charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179) and added the resulting charges to determine the final inflated average caseweighted-standardized charge per case. The applicant calculated a final inflated average caseweighted-standardized charge per case of $75,122 and an average case-weighted threshold amount of $52,216.

The applicant also calculated an average case-weighted standardized charge per case for cUTI and cIAI separately using the same methodology previously described and determined final inflated average case-weighted standardized charges per case of $70,765 for cUTI and $109,403 for cIAI and average case-weighted thresholds of $50,210 for cUTI and $67,531 for cIAI. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in each scenario, the applicant maintained that the technology met the cost criterion.

We agreed with the applicant that it meets the cost criterion and therefore proposed to approve RECARBRIO™ for new technology add-on payments for FY 2021. As previously noted, the applicant stated that RECARBRIO™ can be identified by ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam antiinfective-into central vein, percutaneous approach, new technology group 5).

Based on preliminary information from the applicant at the time of the proposed rule, the cost of RECARBRIO™ is $4,710.37 (which is based on the cost per patient determined using the methodology as previously described in the analysis of the cost criterion). Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving RECARBRIO™ would be $3,532.78 for FY 2021 (that is 75 percent of the average cost of the technology).

We invited public comments on whether RECARBRIO™ meets the cost criterion and our proposal to approve new technology add-on payments for the RECARBRIO™ for FY 2021.

Comment: A commenter supported CMS' proposal to approve new technology add-on payments for FY 2021 for RECARBRIO™ infusion. The commenter also encouraged CMS to extend the duration of eligibility of new technology add-on payment from three to five years, as well as streamline the overall new technology add-on payment process (including submission, tracking, usage and education).

Response: We appreciate the commenter's support for the proposal and other suggestions. We note that the period of time that a technology may receive the new technology add-on payment is limited by statute.

Comment: According to the applicant, RECARBRIO™ was approved by FDA on June 5, 2020 and granted QIDP status for the additional indications of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible gram-negative microorganisms in patients 18 years of ages and older. (As previously noted, RECARBRIO™ received FDA approval on July 16, 2019 for injection in patients 18 years of age and older who have limited or no alternative treatment options for the treatment of the following infections caused by certain susceptible gram-negative bacteria: cUTI including pyelonephritis and cIAI.) Accordingly, the applicant provided an updated cost analysis to incorporate the additional indications to demonstrate that both indications meet the cost criterion.

Response: We appreciate the updated information submitted by the applicant. However, the applicant did not apply for new technology add-on payments for the additional indications of HABP and VABP caused by susceptible gram-negative microorganisms in patients 18 years of ages and older. Therefore, we are unable to consider these additional indications for new technology add on payments for FY 2021.

Based on the information in the applicant's new technology add-on payment application and after consideration of the public comments we received, we believe that RECARBRIO™ meets the cost criterion. As previously discussed, RECARBRIO™ received FDA approval for the treatment of cUTI including pyelonephritis and cIAI for patients 18 years of age and older on July 16, 2019, but was not commercially available until January 6, 2020. Therefore, we are finalizing our proposal to approve new technology add-on payments for RECARBRIO™ for FY 2021, and we consider the beginning of the newness period to commence when the technology became commercially available on January 6, 2020. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the amount by which the costs of the

case exceed the standard MS–DRG payment. As a result, we are finalizing as proposed a maximum new technology add-on payment for a case involving the use of RECARBRIO™ as indicated for the treatment of cUTI and cIAI for patients 18 years of age and older of $3,532.78 for FY 2021 (that is 75 percent of the average cost of the technology). Cases involving the use of RECARBRIO™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes XW033U5 or XW043U5.

(5) XENLETA

Nabriva Therapeutics submitted an application for XENLETA, a pleuromutilin antibacterial agent representing the first intravenous (IV) and oral treatment option from a novel class of antibiotics for community-acquired bacterial pneumonia (CABP). XENLETA is indicated for the treatment of adults with CABP caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.* Per the applicant, XENLETA also has in vitro activity against methicillin resistant *Staphylococcus aureus.*

Per the applicant, pleuromutilins inhibit bacterial protein synthesis by binding to the A- and P-sites of the peptidyl transferase center (PTC) in the large ribosomal subunit of the bacterial ribosome. The applicant asserts that this unique binding site in the highly conserved core of the ribosomal PTC is specific to pleuromutilins, and it confers a lack of cross-resistance with other classes, as well as a low propensity for developing bacterial resistance.

The applicant noted that there are two methods of administering XENLETA. As a tablet containing 600 mg of XENLETA, it is administered orally every 12 hours for a duration of 5 days. As an injection, XENLETA contains 150 mg of the drug and is administered every 12 hours by IV infusion over 60 minutes for a duration of 5 to 7 days, with the option to switch to XENLETA tablets administered every 12 hours to complete the treatment course.

With respect to the newness criterion, the applicant indicated that XENLETA was approved by FDA under the QIDP designation, and granted fasttrack-designation. XENLETA received FDA approval on August 19, 2019 for a new drug application indicated for the oral and IV formulations of XENLETA for the treatment of CABP in adults. The applicant indicated that XENLETA was commercially available on the U.S. market on September 10, 2019 and the slight delay from approval to availability was due to the shipment of drug to the distribution channels.

The applicant's submitted a request for approval of a unique ICD–10–PCS procedure code to identify the administration of XENLETA and was granted approval for the following procedure codes effective October 1, 2020: XW03366 (Introduction of lefamulin anti-infective into peripheral vein, percutaneous approach, new technology group 6), XW04366 (Introduction of lefamulin anti-infective into central vein, percutaneous approach, new technology group 6) or XW0DX66 (Introduction of efamulin anti-infective into mouth and pharynx, external approach, new technology group 6).

With respect to the cost criterion, the applicant presented three scenarios varying in the assumptions regarding the form of XENLETA used to treat the patient and the duration of treatment. For the first analysis, the applicant assumed that a patient population with CABP received 7 days of IV treatment with XENLETA. For the second analysis, the applicant assumed the patient population received 3.2 days of IV treatment with XENLETA before switching to oral XENLETA for 3.8 days. For the third analysis, the applicant assumed the patient population received oral XENLETA for 5 days. The applicant explained that patients receiving XENLETA in the inpatient hospital setting would receive it through IV treatment. However, some patients may be switched to oral form during care, which was observed for some patients in clinical trial. While the applicant does not expect many patients to be treated with only oral XENLETA in the inpatient setting, they conducted a sensitivity analysis based on 5 days of treatment with oral XENLETA, as oral treatment is possible in hospital.

Across all three analyses, the applicant first searched the FY 2018 MedPAR Final Rule Limited Data Set for potential cases representing patients diagnosed with CABP and eligible for treatment with XENLETA. The applicant limited the cohort to cases that had an indication on the claim that the pneumonia was present on admission. The applicant searched for claims that had one of the following ICD–10–CM diagnosis codes as a principal or secondary diagnosis:

ICD-10-CM Diagnosis Code	Description
A48.1	Legionnaires disease
J13	Pneumonia due to Streptococcus pneumonia
J14	Pneumonia due to Haemophilus influenza
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to methicillin susceptible Staphylococcus aureus
J15.7	Pneumonia due to Mycoplasma pneumonia
J15.8	Pneumonia due to other specified bacteria
J15.9	Unspecified bacterial pneumonia
J16.0	Chlamydial pneumonia
J16.8	Pneumonia due to other specified infectious organisms
J17	Pneumonia in diseases classified elsewhere
J18.0	Bronchopneumonia, unspecified organism
J18.1	Lobar pneumonia, unspecified organism
J18.2	Hypostatic pneumonia, unspecified organism
J18.8	Other pneumonia, unspecified organism
J18.9	Pneumonia, unspecified organism

The applicant identified 1,225,713 cases from the FY 2018 MedPAR LDS file spanning 357 MS–DRGs. The applicant then excluded cases that mapped to MS–DRGs with a volume of 10 cases or fewer, resulting in a total of 1,225,561 cases spanning 319 unique MS–DRGs. The applicant considered these cases to be the primary cohort of the cost analysis. The applicant noted that the most common MS–DRGs in the cohort are 871, 193, 194, 291, and 190, which account for 61 percent of cases. The applicant presented the following table of the top 20 MS–DRGs in the primary cohort with more than 10 cases:

MS-DRG	Description
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
175	Pulmonary Embolism with MCC
177	Respiratory Infections and Inflammations with MCC
180	Respiratory Neoplasms with MCC
189	Pulmonary Edema and Respiratory Failure
190	Chronic Obstructive Pulmonary Disease with MCC
193	Simple Pneumonia and Pleurisy with MCC
194	Simple Pneumonia and Pleurisy with CC
195	Simple Pneumonia and Pleurisy without CC/MCC

MS-DRG	Description
207	Respiratory System Diagnosis with Ventilator Support >96 hours
208	Respiratory System Diagnosis with Ventilator Support <=96 hours
280	Acute Myocardial Infarction, Discharged Alive with MCC
291	Heart Failure and Shock with MCC
308	Cardiac Arrhythmia and Conduction Disorders with MCC
377	G.I. Hemorrhage with MCC
682	Renal Failure with MCC
689	Kidney and Urinary Tract Infections with MCC
853	Infectious and Parasitic Diseases with O.R. Procedure with MCC
870	Septicemia or Severe Sepsis with MV >96 hours
871	Septicemia or Severe Sepsis without MV >96 hours with MCC

For all three scenarios, the applicant calculated an average case-weighted unstandardized charge per case of $73,911. The applicant then removed charges for the prior technology being replaced, which included the average charge associated with the cost of antibiotics that are the current standard of care. The applicant varied assumptions by scenario to reflect appropriate substitute treatments for the different forms of XENLETA, as noted previously. For each scenario, the applicant calculated the cost of therapy for each standard of care drug using dosing information, the duration of treatment, and wholesale acquisition costs and converted them to charges using the national pharmacy cost-to-charge ratio published in the FY 2020 IPPS final rule (84 FR 42179). After adjusting for prior technology, the applicant standardized the charges and applied an inflation factor of 11.1 percent, which is the 2-year inflation factor used by CMS to calculate outlier threshold charges in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629), to update the charges from FY 2018 to FY 2020. The applicant added charges for the new technology, which it again calculated using the national pharmacy cost-to-charge ratio.

For all three scenarios, the applicant conducted a sensitivity analysis testing alternative assumptions regarding the charges associated with prior technology that could be replaced by XENLETA. The applicant acknowledged that it is possible for some patients with CABP to receive more than one antibiotic. The applicant examined the cost criterion for each scenario after doubling the charges associated with prior technology to account for multiple antibiotics. Furthermore, the applicant tested alterative assumptions regarding the MS–DRGs that cases representing patients eligible for treatment with XENLETA mapped. Specifically, the applicant examined the cost criterion for the top 10 MS–DRGs, the top 20 MS–DRGs, and the top MS–DRGs that accounted for 75 percent of cases.

Across all three scenarios and the sensitivity analyses testing alternative assumptions, the applicant determined that the final inflated average standardized charge per case exceeded the case-weighted threshold, with the difference ranging from $4,547 to $17,907. The following table summarizes the results of the applicant's cost analyses. The applicant maintained that XENLETA meets the cost criterion.

		Case-Weighted Threshold	Final Inflated Average Case-Weighted Standardized Charge Per Case	Difference
Scenario 1 (Patient with CABP treated with 7 days of IV XENLETA)	**100 percent of cases**	$61,896	$75,459	$13,563
	Top 10 MS-DRGs	$51,730	$56,277	$4,547
	Top 25 MS-DRGs	$54,859	$60,989	$6,130
	75 percent of cases	$53,908	$59,336	$5,428
Scenario 2 (Patient with CABP treated with Blend of IV and Oral XENLETA)	**100 percent of cases**	$61,896	$77,030	$15,134
	Top 10 MS-DRGs	$51,730	$57,849	$6,119
	Top 25 MS-DRGs	$54,859	$62,560	$7,707
	75 percent of cases	$53,908	$60,908	$7,000
Scenario 3 (Patient with CABP treated with oral XENLETA for 5 days)	**100 percent of cases**	$61,896	$78,803	$17,907
	Top 10 MS-DRGs	$51,730	$60,642	$8,912
	Top 25 MS-DRGs	$54,859	$65,349	$10,490
	75 percent of cases	$53,908	$63,698	$9,790

In the proposed rule, we stated that we agreed with the applicant that XENLETA meets the cost criterion and therefore proposed to approve XENLETA for new technology add-on payments for FY 2021. As previously noted, the applicant has received unique ICD–10–PCS procedure codes to identify cases involving the administration of XENLETA.

In its application, the applicant stated that XENLETA is commercially available in two dosage forms (Intravenous and Oral). According to the applicant, the pricing for each dosage form is $102.50 per single use vial of XENLETA and $137.50 for one tablet of XENLETA. The recommended dosage per the applicant is 150 mg every 12 hours by intravenous (IV) infusion for 5 to 7 days or one 600 mg tablet every 12 hours for 5 days. The applicant estimates that the cost per patient of XENLETA is $1,701 based on the combination of IV and oral usage in two of the applicants' clinical trials. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of XENLETA would be $1,275.75 for FY 2021 (that is 75 percent of the average cost of the technology).

We invited public comments on whether XENLETA meets the cost criterion and our proposal to approve new technology add-on payments for XENLETA for FY 2021.

Comment: Commenters supported our proposal to approve XENLETA for new technology add-on payments for FY 2021.

Response: We appreciate the commenters' support for our proposal.

Based on the information in the applicant's new technology add-on payment application and after consideration of the public comments, we believe that XENLETA meets the cost criterion. As previously discussed, XENLETA received FDA approval for use in the treatment of community-acquired bacterial pneumonia (CABP) in adults on August 19, 2019 but was not commercially available until September 10, 2019. Therefore, we are finalizing our proposal to approve new technology add-on payments for XENLETA for FY 2021, and we consider the beginning of the newness period to commence on September 10, 2019, which is the date that XENLETA became commercially available. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the amount by which the costs of the case exceeds the standard MS–DRG payment. As a result, we are finalizing as proposed a maximum new technology add-on payment for a case involving the use of XENLETA of $1,275.75 for FY 2021 (that is 75 percent of the average cost of the technology). Cases involving the use of XENLETA that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: XW03366, XW04366 or XW0DX66.

(6) ZERBAXA®

Merck submitted an application for new technology add-on payments for ZERBAXA® for FY 2021. ZERBAXA® (ceftolozane and tazobactam) is a combination of ceftolozane, a cephalosporin antibacterial; and tazobactam, a β-lactamase inhibitor (BLI), indicated in patients 18 years or older for the treatment of the following infections caused by designated susceptible microorganisms:

- Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole;
- Complicated Urinary Tract Infections (cUTI), Including Pyelonephriti;
- Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

According to the applicant, FDA initially approved ZERBAXA® on December 19, 2014 for the treatment of complicated intra-abdominal infections (cIAI) and for complicated urinary tract infections (cUTI) under a New Drug Application (NDA). ZERBAXA® was then approved on June 3, 2019 for the indication of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), also under a NDA. The applicant noted that ZERBAXA® was designated as a Quality Infectious Disease Product (QIDP) as well as provided Fast Track and Priority Review consideration by FDA. The applicant also indicated that ZERBAXA® was commercially available on the U.S. market upon FDA approval. We believe only the indication approved in 2019 for treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) is eligible for new technology add on payments for FY 2021 because the first indication was approved in 2014 and is therefore beyond the 3-year newness period.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code to identify the administration of ZERBAXA® and was granted approval for FY 2021 for the following procedure codes effective October 1, 2020: XW03396 or XW04396.

According to the applicant, to reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA® and other antibacterial drugs, ZERBAXA® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. According to the applicant, when culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

The applicant explained that the recommended dosage of ZERBAXA® for injection when used for HABP/VABP is 3 g (ceftolozane 2 g and tazobactam 1 g) administered every 8 hours by intravenous infusion over 1 hour in patients 18 years or older and with a creatinine clearance (CrCl) greater than 50 mL/min. The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress. Dose adjustment is required for patients with CrCl 50 mL/min or less. All doses of ZERBAXA® are administered over 1 hour. For patients with changing renal function, CrCl is monitored at least daily and dosage of ZERBAXA® adjusted accordingly.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to identify the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving ZERBAXA® would be mapped. According to the applicant, ZERBAXA® is indicated for the treatment of hospitalized patients who have been diagnosed with cUTI, cIAI, VABP, or HABP conditions. The applicant conducted multiple analyses based on ICD–10–CM diagnosis codes for various scenarios involving patients diagnosed with cUTI, cIAI, VABP, or HABP. The applicant stated that cases representing patients who may be eligible to receive treatment through the administration of ZERBAXA® are identified with ICD–10–PCS codes 3E03329 (Introduction of other anti-infective into peripheral vein, percutaneous approach) or 3E04329 (Introduction of other antiinfective—into central vein, percutaneous approach). For the purposes of analyzing the cost criterion for this technology for new technology add-on payment for FY 2021, we are only discussing the applicant's cost analysis related to the HABP and VABP

indications because, as we noted previously, the first indications (cUTI, cIAI) were approved in 2014 and are therefore beyond the 3-year newness period. For the HABP and VABP scenarios, the applicant submitted the following three cost analysis scenarios: Cases with a HABP diagnosis only, cases with a VABP diagnosis only and cases with either a HABP or VABP diagnosis. For all three scenarios, the applicant calculated the average charges per case for each MS–DRG without standardizing the charges. Next, the applicant removed 100 percent of the drug charges from the relevant cases to conservatively estimate the charges for drugs that potentially may be replaced by or avoided through use of ZERBAXA®. After removing these drug charges from unstandardized average charge amounts, the applicant calculated the average standardized charge per case for each MS–DRG. Then, the applicant inflated the standardized average charges by 11.1 percent, which is the 2-year inflation factor used by CMS to calculate outlier threshold charges in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629), to update the charges from FY 2018 to FY 2020. The applicant added charges for the new technology, which it again calculated using the national pharmacy cost-to-charge ratio. Finally, the applicant calculated the final inflated average case-weighted standardized charge per case as well as the case-weighted threshold amount. The following table summarizes the results of the applicant's cost analyses. The applicant maintained that ZERBAXA® meets the cost criterion.

Scenario	Cases	Case-Weighted Threshold	Final Inflated Average CaseWeighted- Standardized Charge Per Case	Difference
Cases with VABP	6,880	$203,394	$306,882	$103,488
Cases with HABP	121,748	$114,725	$188,193	$73,468
Cases with Either VABP or HABP	124,402	$115,090	$187,293	$72,203

As stated in the proposed rule, we agree with the applicant that ZERBAXA® meets the cost criterion and therefore proposed to approve ZERBAXA® for new technology add-on payments for FY 2021. As previously noted, the applicant has received unique ICD–10–PCS procedure codes to identify cases involving the administration of ZERBAXA®.

Based on preliminary information from the applicant at the time of the proposed rule, the cost of ZERBAXA® is $2,449.31. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of ZERBAXA® would be $1,836.98 for FY 2021 (that is 75 percent of the average cost of the technology).

We invited public comments on whether ZERBAXA® meets the cost criterion and our proposal to approve new technology add-on payments for ZERBAXA® for FY 2021.

Comment: Commenters agreed that ZERBAXA® meets the cost criterion and supported CMS's proposal to approve ZERBAXA® for new technology add-on payments for FY 2021.

Response: We thank the commenters for their support.

Based on the information in the applicant's new technology add-on payment application and after consideration of the public comments, we believe that ZERBAXA® meets the cost criterion. As previously discussed, ZERBAXA® received FDA approval on June 3, 2019 for the indication of HABP/VABP and was commercially available on the U.S. market upon FDA approval. Therefore, we are finalizing our proposal to approve new technology add-on payments for ZERBAXA® for FY 2021, and we consider the beginning of the newness period to commence when the technology received FDA approval on June 3, 2019. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the amount by which the costs of the case exceed the standard MS–DRG payment. As a result, we are finalizing as proposed a maximum new technology add-on payment for a case involving the use of ZERBAXA® of $1,836.98 for FY 2021 (that is 75 percent of the average cost of the technology). Cases involving the use of ZERBAXA® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW03396 or XW04396.

7. Technical Revision to the New Technology Add-On Payment Regulations at 42 CFR 412.88

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300, and 42612), we finalized an increase in the new technology add-on payment percentage. Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. We also finalized a separate increase in the new technology add-on payment percentage to 75 percent for a new technology that is a medical product designated by FDA as a QIDP. Under this finalized policy, unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for a medical product designated by FDA as a QIDP) of the estimated costs of the new technology or medical service. We also finalized revisions to paragraphs (a)(2) and (b) under § 412.88 to reflect these changes to the calculation of the new technology add-on payment amount beginning in FY 2020, including the finalized percentage for a medical product designated by FDA as a QIDP. Specifically, the new technology add-on payment percentage of 65 percent for a new technology other than a medical product designated by FDA as a QIDP is

set forth in § 412.88(a)(2)(ii)(A). The new technology add-on payment percentage of 75 percent for a medical product designated by FDA as a QIDP is set forth at § 412.88(a)(2)(ii)(B). However, in our revision to paragraph (a)(2)(ii), in setting forth the new technology add-on payment amounts for discharges occurring on or after October 1, 2019, we made an inadvertent error when referencing the separate new technology add-on payment percentage for QIDPs under § 412.88(a)(2)(ii)(B). Specifically, in referencing the add-on percentage for QIDPs, § 412.88(a)(2)(ii)(A) refers to ''paragraph (a)(2)(ii)(*2*) of this section'' when the correct citation should be ''paragraph (a)(2)(ii)(B) of this section''. In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.88(a)(2)(ii)(A) to correct this technical error. No comments were received regarding this proposal. Therefore, in this final rule, we are finalizing this revision as proposed.

8. Technical Clarification to the Alternative Pathway for Certain Transformative New Devices

As described previously, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new technology add-on payments for certain transformative new devices. Under the existing regulations at § 412.87(c), to be eligible for approval under this alternative pathway, the device must be part of FDA's Breakthrough Devices Program and have received FDA marketing authorization.

We have received questions from the public regarding CMS's intent with respect to the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices at § 412.87(c). Some of the public appear to assert that so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program, the technology would meet the marketing authorization requirement at § 412.87(c). For example, consider a device that received FDA marketing authorization in 2019 for use in the heart. The same device is then designated by FDA as part of the Breakthrough Devices Program for use in the liver in 2020, but has not yet received marketing authorization for indicated use in the liver. Some of the public have asserted that in such a scenario, the original marketing authorization for use in the heart could be used with FDA's Breakthrough Device indication for use in the liver to qualify under the alternative pathway for certain transformative new devices and receive new technology add-on payments for use in the liver in FY 2021. Because of this potential confusion, we clarified in the proposed rule that, consistent with our existing policies for determining newness where a product has more than one indication, an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment, for purposes of approval under the alternative pathway for certain transformative devices.

Section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. As explained in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Generally, we use FDA approval (that is, marketing authorization) as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In some specific circumstances, we have recognized a date later than FDA approval as the appropriate starting point for the 2-year to 3-year period. The costs of the new medical service or technology, once paid for by Medicare for this 2-year to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, we limit the add-on payment window for those technologies that have passed this 2-to 3-year timeframe. In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46915), we also indicated that an existing technology can receive new technology add on payments for a new use or indication. While we recognize that a technology can have multiple indications, each indication has its own newness period and must meet the new technology add on payment criteria. The applicable criteria will depend on whether the technology is eligible for an alternative new technology add-on payment pathway. However, each indication for the technology is evaluated separately from any other indication, including with respect to the start of the newness period, to determine whether the technology is eligible for new technology add-on payments when used for that indication.

Based on this policy, using the previous example, the newness period for the heart indication began in 2019 when the technology received marketing authorization from FDA for that indication, while the newness period for the liver indication would begin when the device receives marketing authorization specifically indicated for the liver. These are two distinct newness periods. Consistent with this policy, the newness period that began with the original marketing authorization for indicated use in the heart cannot be combined with FDA's Breakthrough Device indication for use in the liver for purposes of the marketing authorization required for approval under the alternative pathway to receive new technology add-on payments in FY 2021.

In the FY 2021 IPPS/LTCH PPS proposed rule, we stated that to address this potential confusion, we are clarifying our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and making a conforming change to the regulations at § 412.87(c)(1). Specifically, with regard to the eligibility criteria for approval under the alternative pathway for certain transformative new devices, we proposed to amend the regulations in § 412.87(c)(1) to state that ''A new medical device is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.'' We also proposed to make similar amendments to the regulations at § 412.87(d) for the alternative pathway for certain antimicrobial products, as discussed in section II.G.9.b. of this preamble of this final rule.

Comment: Commenters were mostly supportive of the policy clarification. Commenters supportive of the clarification indicated that they support CMS's efforts to recognize devices that are part of the FDA Breakthrough Devices Program and applauded CMS for providing revisions to these

regulations to provide clarification to the ''market authorization'' component.

One commenter requested clarification if a device that received FDA Breakthrough designation and was approved for marketing under the Humanitarian Device Exemption (HDE) pathway for a HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), would still be eligible for the alternative new technology add-on payment pathway based on the FDA Breakthrough designation.

Furthermore, two commenters (including the applicant for the Nanoknife, which did not meet the deadline of July 1 for FDA approval or clearance, as discussed previously) did not support this policy clarification. According to these commenters, if the proposed conforming changes are finalized, an otherwise broad eligibility standard would become limited. These commenters stated that the requirement that a new medical device must have received FDA marketing authorization sets a broad standard and the current regulation has no explicit limit to the type of marketing authorization and no mandate that the FDA marketing authorization indication be the same as the indication covered by the Breakthrough Device designation.

According to the same two commenters, the policy clarification also constitutes a new regulatory provision that will limit new technology add-on payment eligibility to only those devices where the marketing authorization indication matched exactly the Breakthrough Device indication. The commenters stated that although it was described as a technical clarification, the denial of access to new-technology add-on payment for Medicare beneficiaries makes the proposed amendment a significant regulatory change. According to the commenters, consistent with the Administrative Procedure Act, the proposed new regulatory language must first go through a full notice and comment period prior to finalizing any new changes. Then, according to the commenters, the earliest the new regulation could be applied is in the next regulatory cycle, beginning with applications submitted for new technology add-on payments for FY 2022. Finally, they asserted that with what they described as CMS' application of the proposal retroactively, applicants for new technology add-on payment for FY 2021 had no prior notice in either the regulations or CMS' new technology add-on payment application, which caused the denial of new technology add-on payment to applicants and Medicare beneficiaries.

The same two commenters also suggested that CMS should align eligibility for new technology add-on payment with FDA's IDE determination which supports hospitals providing innovative care early in product development. According to the commenters, CMS should include in the regulation at § 412.87(c)(1) that an IDE can qualify as marketing authorization and that the IDE determination can match the Breakthrough Designation indication for new technology add-on payment eligibility criteria. According to the commenters, waiting until traditional PMA or 510(k) marketing authorization will delay the availability of new technology add-on payment for years which can have a serious adverse impact on patients.

Response: We appreciate commenters' support regarding the clarification that a new medical device under the alternative pathway for certain transformative new devices must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation.

We disagree with the commenters that asserted this technical clarification is instead a significant change in our new technology add-on payment policy and that the associated conforming revisions are a significant regulatory change. This technical clarification, and the proposed conforming change to the regulations, are consistent with CMS's longstanding policy to require marketing authorization for the specific indication for which the applicant is seeking the new technology add-on payment. As discussed in the proposed rule and previously in this final rule, in the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46915), we indicated that an existing technology can receive new technology add-on payments for a new use or indication. As we also discussed in the proposed rule, while we recognize that a technology can have multiple indications, each indication has its own newness period and must meet the new technology add-on payment criteria. This is consistent with how we have evaluated prior applications for the new technology add-on payment, as discussed in prior rulemaking (InFUSE™ Bone Graft (Bone Morphogenetic Proteins (BMPs) for Tibia Fractures 69 FR 49010, VERASENSE™ Knee Balancer System 80 FR 49471, Stelara® 82 FR 38216, KYMRIAH and YESCARTA 83 FR 41285, Titan Spine nanoLock® 83 FR 41322, ZEMDRI™ 83 FR 41327). The applicable criteria will depend on whether the technology is eligible for an alternative new technology add-on payment pathway, however the submission of an application under such an alternative pathway does not change that each indication for the technology will be evaluated separately from any other indication, including with respect to the start of the newness period, to determine whether the technology is eligible for new technology add-on payments when used for that indication. CMS did not modify this longstanding policy for evaluating whether a technology with multiple indications has received the required marketing authorization when it adopted the alternative pathway for certain transformative new devices in FY 2020. We believe the commenter is asking CMS to evaluate a technology inconsistent with this longstanding policy and to start the newness period prior to the time a product receives marketing authorization. As previously explained, and in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Our longstanding policy explained previously has applied this intent to new technology add-on payment applications for new indications of an existing technology and initial uses of a new technology. The device would remain eligible to apply for the new technology add-on payment under this alternative pathway for the indication covered by the Breakthrough Devices Program for a future fiscal year.

For these reasons, we disagree with the commenters that our clarification and proposed conforming amendment are a change to the existing eligibility standards for new technology add-on payments. However, even if this were to be considered a change in policy rather than a clarification, CMS would not be applying the proposal retroactively, as asserted by the commenters, because the policy would apply only prospectively to future payments beginning with the start of the next fiscal year, after finalization of the policy through notice and comment rulemaking.

Regarding the request for clarification on whether a device that received FDA Breakthrough Device designation and was approved for marketing under the HDE pathway for a HUD (Section 520(m) of the FD&C Act), would still be eligible for the alternative new

technology add-on payment pathway based on the FDA Breakthrough Device designation, we are unsure what specifically the commenter is requesting clarification on, and refer the commenter to the eligibility criteria for approval under the alternative pathway for certain transformative new devices at § 412.87(c)(1). Additionally, as previously stated and in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. If a product was on the market for 5 years and then the device became part of FDA's Breakthrough Devices Program, it would not be eligible for new technology add-on payments since the device is already reflected in the DRG weights and is beyond the 2–3 year newness period. Conversely, if a product received marketing authorization for the indication covered by the Breakthrough Devices Program designation within the past 2 to 3 years, it may be eligible for new technology add-on payments under the alternative pathway for certain transformative new devices; however, we would encourage any prospective applicant to review the eligibility criteria for approval under the alternative pathway for certain transformative new devices to evaluate whether they should apply for the new technology add-on payment. We also refer the commenter the FY 2010 IPPS Final Rule (74 FR 43819) which discusses the Spiration® IBV® Valve System which received a HDE approval from the FDA and was approved for new technology add-on payments for FY 2010.

Regarding the suggestion that CMS should include in the regulation at § 412.87(c)(1) that an IDE can qualify as marketing authorization and that the IDE determination can match the Breakthrough Designation indication for new technology add-on payment eligibility criteria, we disagree. As discussed previously, it is our understanding that an IDE allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data prior to the device receiving FDA marketing authorization (that is, received PMA approval, 510(k) clearance, or the granting of De Novo classification request). Therefore, we do not believe it would be appropriate to update the regulations to reflect that an IDE qualifies as marketing authorization.[429]

After consideration of the comments received and for the reasons discussed, we are finalizing our proposed conforming change to the regulations at § 412.87(c)(1) to reflect our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. Specifically, with regard to the eligibility criteria for approval under the alternative pathway for certain transformative new devices, we are finalizing our proposal to amend the regulations in § 412.87(c)(1) to state that ''A new medical device is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.'' We note that we are also finalizing our proposal to make similar amendments to the regulations at § 412.87(d) for the alternative pathway for certain antimicrobial products, as discussed in section II.G.9.b. of this preamble of this final rule.

9. Revisions to New Technology Add-On Payments for Certain Antimicrobial Products

a. Background

In the FY 2020 IPPS/LTCH PPS final rule, after consideration of public comments, we finalized changes to the new technology add-on payment policy related to certain antimicrobial products. These changes were finalized in recognition of the significant concerns related to antimicrobial resistance and its serious impact on Medicare beneficiaries and public health overall, and consistent with the Administration's commitment to address issues related to antimicrobial resistance, in order to help secure access to antibiotics, and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible. Firstly, as described earlier in this section, we finalized an alternative new technology add-on payment pathway for a product that is designated by FDA as a QIDP. Under this alternative pathway, at existing § 412.87(d), for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a technology receives FDA's QIDP designation and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this pathway, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP will need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(d)(3) (84 FR 42292 through 42297).

In addition, beginning with FY 2020, we adopted a general increase in the maximum new technology add-on payment amount from 50 percent to 65 percent; however, we adopted a higher increase to 75 percent for a product that is designated by FDA as a QIDP. Therefore, under existing § 412.88(a)(2)(ii)(B), for a new technology that is a medical product designated by FDA as a QIDP, the new technology add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment (84 FR 42297 through 42300).

We stated that we believe Medicare beneficiaries may be disproportionately impacted by antimicrobial resistance, due in large part to the elderly's unique vulnerability to drug-resistant infections (for example, due to age-related and/or disease-related immunosuppression and greater pathogen exposure via catheter use). As such, antimicrobial resistance results in a substantial number of additional hospital days for Medicare beneficiaries, resulting in significant unnecessary health care expenditures. In November 2019, the CDC released its updated ''Antibiotic Resistance Threats in the United States'' (AR Threats Report) [430] indicating that antibiotic-resistant bacteria and fungi cause more than 2.8 million infections and 35,000 deaths in the United States each year. This report also shows that there were nearly twice as many annual deaths from antibiotic resistance as CDC originally reported in 2013, and underscores the continued threat of antibiotic resistance in the U.S. This recent information highlights the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance of this issue both with respect to Medicare beneficiaries and public health overall. In this section of the final rule, we

[429] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide.*

[430] *https://www.cdc.gov/drugresistance/biggest-threats.html.*

discuss our proposals and final policies for FY 2021 regarding new technology add-on payments and certain antimicrobials, including QIDPs.

b. Changes and Technical Clarification to the Alternative Pathway for Certain Antimicrobial Products

As described previously, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new technology add-on payments for certain antimicrobial products. Under the existing regulations at § 412.87(d), to be eligible for approval under this alternative pathway, the antimicrobial product must be designated by FDA as a QIDP and have received FDA marketing authorization. Under this alternative pathway, such a QIDP will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

FDA also has the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), which encourages the development of safe and effective drug products that address unmet needs of patients with serious bacterial and fungal infections.[431] [432] Specifically, an antibacterial or antifungal drug approved under the LPAD pathway is used to treat a serious or life-threatening infection in a limited population of patients with unmet needs. We stated in the proposed rule that we believe that in order to address the continued issues related to antimicrobial resistance discussed previously, as well as further help to support access to antibiotics and improve health outcomes for Medicare beneficiaries, it is appropriate to expand our policy for an alternative new technology add-on payment pathway for a product that is designated by FDA as a QIDP to include products approved as a LPAD as well. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway as well to further address the continued issues related to antimicrobial resistance discussed previously. Under this proposed policy, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial drug is approved by FDA under the LPAD pathway it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this proposal, an antimicrobial product that is approved by FDA under the LPAD pathway will need to meet the cost criterion under § 412.87(b)(3).

We proposed to revise § 412.87(d)(1) to reflect this proposal, by adding drugs approved under FDA's LPAD pathway to the current alternative new technology add-on payment pathway for QIDPs at proposed new § 412.87(d)(1)(ii), beginning with discharges occurring on or after October 1, 2021. We also proposed to revise the title of existing § 412.87(d) to refer more broadly to ''certain antimicrobial products'' rather than specifying in this title the particular FDA programs for antimicrobial products (that is, QIDPs and LPADs) that are the subject of this alternative new technology add-on payment pathway.

As we noted in the proposed rule, FDA may approve a drug under the LPAD pathway if it meets certain statutory standards for approval, as applicable, including that FDA receives a written request from the sponsor to approve the drug as a limited population drug. Sponsors seeking approval of a drug under the LPAD pathway are not precluded from seeking designation or approval under any other applicable provision for which the drug otherwise qualifies (for example, fast track designation, breakthrough therapy designation, regenerative medicine advanced therapy designation, accelerated approval, priority review designation). A sponsor who seeks approval of a drug under the LPAD pathway may also seek designation, as applicable, for other programs, including QIDP or orphan drug designation. Although FDA may provide advice on potential eligibility, FDA intends to make the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. (For additional information, see *https://www.fda.gov/media/113729/download*.)

We stated in the proposed rule that as such, an applicant that has not received FDA approval and which has requested approval under the LPAD pathway may not know with certainty at the time it applies for new technology add-on payments under the proposed expanded alternative pathway for certain antimicrobial products whether it will qualify for approval under that pathway. As noted previously in section II.G.1.d. of the preamble of this final rule, CMS will review the application based on the information provided by the applicant under the alternative pathway specified by the applicant. If the applicant drug ultimately does not receive approval under the LPAD pathway (but receives FDA approval otherwise) and is not designated as a QIDP, the technology would not be eligible for the alternative pathway for certain antimicrobial products and the applicant would need to re-apply for new technology add-on payments under the traditional pathway at § 412.87(b) for the following fiscal year in order to seek approval for new technology add-on payments.

Comment: Several commenters supported this proposal. These commenters described the proposal as a common-sense solution that will address concerns from hospitals regarding inadequate payment for new antimicrobial products. Commenters also indicated that the proposal works hand-in-hand with the policy change finalized in the FY 2020 IPPS/LTCH PPS final rule regarding the alternative pathway for QIDPs.

However, other commenters were not supportive of this proposal. MedPAC expressed that it did not support the use of FDA's LPAD for qualification for new technology add-on payment unless the drug in question also meets the current substantial clinical improvement criterion and there is some evidence that the new drug results in improved care for beneficiaries. According to MedPAC, the FDA approval process may or may not include the new device or pharmaceutical's safety or effectiveness with regard to the Medicare population and Medicare should not pay more for technological advances that have not yet been proven to provide better outcomes for beneficiaries. MedPAC also stated that it is concerned that, if this proposal is adopted, the additional payment would also provide an incentive for increased use (including off-label use) of drugs approved under the LPAD pathway. MedPAC explained that the drugs approved under the LPAD pathway are for a limited population, based on a more flexible risk-benefit assessment, and prescribing these products outside of the targeted approved indication could endanger patients unnecessarily. Finally, MedPAC conveyed that if CMS finalizes its proposal to expand the alternative pathway to include products approved under the LPAD pathway,

[431] Section 506(h) of the FD&C Act, 21 U.S.C. 356(h).

[432] *https://www.fda.gov/media/113729/download.*

CMS could attempt to mitigate incentives for off-label use by limiting new technology add-on payments to cases that meet FDA's approved and targeted indications.

According to a commenter, current and proposed reforms are insufficient to ensure patients have access to effective antimicrobial treatments and lack significant impact on the AMR crisis. The commenter stated that while the increase in new technology add-on payment for QIDPs from 50 percent to 75 percent in the FY 2020 IPPS/LTCH PPS final rule was appreciated and a step in the right direction, the change has proven to be ineffective in promoting increased use of the new technology add-on payment pathway, thereby limiting the impact of this reform on patient access to novel antimicrobials, the sustainability of the antimicrobial marketplace, and the crisis of AMR generally. This commenter, in addition to a few other commenters, went on to say that the proposal to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway will not effectively broaden or increase the impact of the new technology add-on payment program for antimicrobials, as drugs that qualify for LPAD will likely also have QIDP designation and are therefore already eligible for the alternative new technology add-on payment pathway. Instead, the commenters suggested the expansion of the alternative new technology add-on payment pathway so that it may be applied more broadly to achieve greater overall impact. Specifically, these commenters suggested the expansion include eligible products beyond LPAD and QIDP such as biologics, other non-traditional therapies that treat or prevent infections caused by a qualifying pathogen, as well as drugs that are approved by FDA to treat COVID–19.

Similar to the comments received in response to the FY 2020 IPPS/LTCH PPS proposed rule, commenters requested that CMS extend or develop similar alternative new technology add-on payment pathways for all expedited FDA pathways (for example, Fast Track, Accelerated Approval, Breakthrough Therapy, and Priority Review, including other categories of technologies such as those with a Regenerative Medicine Advanced Therapy (RMAT) designation, devices granted a HDE.

Response: We appreciate the commenters' support of the proposed expansion of the current alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway.

In response to comments that requested that the alternative inpatient new technology add-on payment pathway be extended to, or an alternative pathway similarly be created for, drugs and biologicals (that is, Priority Review, Accelerated Approval, Fast Track, and Breakthrough Therapy, including other categories of technologies such as those with a RMAT designation, devices granted a HDE, we continue to recognize that the goal of facilitating access to new technologies for Medicare beneficiaries could also apply to other special designations for drugs or devices. However, as we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42295 through 42296), we continue to believe that making this policy applicable to drugs more generally would further increase incentives for innovation but without decreasing cost, a key priority of this Administration. We also continue to believe that, in general, it is prudent to gain experience under the alternative pathway for certain transformative new devices before expanding it to other special designations to allow us to evaluate the benefits of this alternative pathway to facilitate beneficiary access to transformative new medical devices as well as any other considerations that may come to light after implementation of this new pathway. We will continue to consider these issues for future rulemaking, including the suggestions to develop additional criteria to qualify under an alternative pathway for technologies that receive FDA marketing authorization under or are designated for an FDA expedited program for drugs or devices.

In response to the commenter that did not support the use of FDA's LPAD for qualification for new technology add-on payment unless the drug in question also meets the current substantial clinical improvement criterion and unless there is some evidence that the new drug results in improved care for beneficiaries, and expressed concern regarding the potential for additional Medicare program expenditures, as we stated in response to similar concerns in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42295), we believe that with respect to these technologies, even though, as the commenter may assert, there may be less certainty of clinical benefit or data representing the Medicare beneficiary population as compared to the evidence standard for substantial clinical improvement under the current new technology add-on payment policy, the benefits of providing early access to critical and life-saving new cures and technologies that improve beneficiary health outcomes support expanding this alternative pathway. Additionally, while we continue to appreciate the commenter's concern regarding additional Medicare program expenditures, for the previously stated reasons, in order to address the significant ongoing concerns related to the public health crisis represented by antimicrobial resistance, consistent with the Administration's commitment to address issues related to antimicrobial resistance, and to continue to help secure access to antibiotics and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible, we believe it is appropriate to further facilitate beneficiary access to antimicrobial resistant products by expanding this alternative pathway to include products approved through FDA's LPAD pathway.

In response to the comment suggesting that CMS mitigate incentives for off-label use by limiting new technology add-on payment to cases that meet FDA's approved and targeted indications, we note that when CMS approves a new technology add-on payment for any technology, it is based on the applicant's FDA indicated market authorization use, and payment is limited to cases involving the use of technology for the indication for which the new technology add-on payment application was approved.

Finally, in response to the commenters' concern that the proposal will not effectively broaden or increase the impact of the new technology add-on payment program for antimicrobials, as drugs that qualify for LPAD will likely also have QIDP designation and are therefore already eligible for the alternative new technology add-on payment pathway, we disagree. As we discussed in the proposed rule, although FDA may provide advice on potential eligibility, FDA intends to make the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. As such, an applicant that has not received FDA approval and which has requested approval under the LPAD pathway may not know with certainty at the time it applies for new technology add-on payments under the proposed expanded alternative pathway for certain antimicrobial products whether it will qualify for approval under that pathway. Although we acknowledge, as we also discussed in the proposed rule, that a sponsor who seeks approval of a drug under the LPAD pathway may also seek designation, as applicable, for other

programs including QIDP or orphan drug designation, resulting in more than one FDA designation (LPAD and QIDP) for the same drug, there may also be instances where a drug receives only one of these two designations or one earlier than the other. Therefore, CMS believes this proposed expansion of the alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway is a reasonable approach to broadening, rather than minimizing, access to antimicrobial products.

Regarding the requests to expand the alternative new technology add-on payment pathway to include eligible products beyond LPAD and QIDP such as biologics, other non-traditional therapies that treat or prevent infections caused by a qualifying pathogen, as well as drugs that are approved by FDA to treat COVID–19, while we recognize that the goal of facilitating access to antimicrobial products for Medicare beneficiaries could also apply to other designations, similar to our discussion previously, in general we believe it is prudent to gain experience under this newly expanded alternative pathway for certain antimicrobial products, before further expanding it to other special designations, to allow us to evaluate the benefits of this expansion to facilitate beneficiary access to antimicrobial products as well as any other considerations that may come to light after implementation of this expanded pathway. We will keep these suggestions in mind for consideration in future rulemaking.

After consideration of the comments received and for the reasons explained previously, we are finalizing our proposal to expand our current alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway. Under this final policy, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial drug receives market authorization from FDA under the LPAD pathway it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this final policy, an antimicrobial product that receives market authorization by FDA under the LPAD pathway will need to meet the cost criterion under § 412.87(b)(3).

We received no comments on our proposed amendments to the regulations to reflect this policy. Therefore we are finalizing our proposal to revise § 412.87(d)(1) to reflect this final policy, by adding drugs approved under FDA's LPAD pathway to the current alternative new technology add-on payment pathway for QIDPs at new § 412.87(d)(1)(ii), beginning with discharges occurring on or after October 1, 2021. We are also finalizing our proposal to revise the title of existing § 412.87(d) to refer more broadly to ''certain antimicrobial products'' rather than specifying in this title the particular FDA programs for antimicrobial products (that is, QIDPs and LPADs) that are the subject of this alternative new technology add-on payment pathway.

We also proposed to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway, from 65 percent to 75 percent, consistent with the new technology add-on payment percentage that currently applies for a product that is designated by FDA as a QIDP. As previously noted, an antibacterial or antifungal drug approved under the LPAD pathway is used to treat a serious or life-threatening infection in a limited population of patients with unmet needs, and therefore we stated in the proposed rule that we believe increasing the add-on payment amount for these products would further the goal of helping secure access to antibiotics and improving health outcomes for Medicare beneficiaries to address the continued significant concerns related to antimicrobial resistance as discussed previously. Therefore, we proposed to revise § 412.88(a)(2)(ii)(B) and (b)(2) by adding products approved under FDA's LPAD pathway, beginning with discharges occurring on or after October 1, 2020.

We did not receive any comments on our proposal to increase the maximum new technology add-on payment percentage for products approved under FDA's LPAD pathway. Therefore, we are also finalizing our proposal to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway, from 65 percent to 75 percent, consistent with the new technology add-on payment percentage that currently applies for a product that is designated by FDA as a QIDP. Therefore, we are revising § 412.88(a)(2)(ii)(B) and (b)(2) by adding products approved under FDA's LPAD pathway, beginning with discharges occurring on or after October 1, 2020.

In addition to adding drugs approved under FDA's LPAD pathway to the alternative new technology add-on payment pathway for certain antimicrobial products, we stated in the proposed rule that we are clarifying our policy regarding marketing authorization for QIDPs. As discussed previously, we stated that we have received questions from the public regarding the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices, and are therefore clarifying our policy regarding the marketing authorization requirement under this pathway and proposing conforming amendments to the regulations at § 412.87(c)(1). We refer the reader to the previous discussion in section II.G.8. of this preamble of this final rule for complete details regarding this clarification.

The current regulations at § 412.87(d)(1) regarding the alternative pathway for new technology add-on payments for certain antimicrobial products also require marketing authorization for a QIDP to be eligible for approval under this pathway. Therefore, similar to the clarification regarding the transformative new devices alternative pathway, we stated in the proposed rule that we are clarifying that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. We proposed to amend the regulations at § 412.87(d)(1) describing the alternative pathway for QIDPs (which, as amended, would appear at § 412.87(d)(1)(i)) to state that ''A new medical product is designated by FDA as a Qualified Infectious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation.''

We did not receive comments on our proposal to amend the regulations at § 412.87(d)(1) to clarify that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. Therefore, we are finalizing this amendment as proposed.

c. Change to Announcement of Determinations and Deadline for Consideration of New Medical Service or Technology Applications for Certain Antimicrobial Products

As noted previously, in the FY 2009 IPPS final rule (73 FR 48562), we

amended § 412.87(c) (now § 412.87(e) of the existing regulations) to specify that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. We stated that this deadline would provide us with enough time to fully consider all of the new medical service or technology add-on payment criteria for each application and maintain predictability in the IPPS for the coming fiscal year. We also stated and further explained that we believe that July 1 of each year provides an appropriate balance between the necessity for adequate time to fully evaluate the applications, the requirement to publish the IPPS final rule by August 1 of each year, and the commenters' concerns that potential new technology applicants have some flexibility with respect to when their technology receives FDA approval or clearance.

We continue to believe that our policy of requiring FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered appropriately balances the length of time required to fully consider all of the new medical service or technology add-on payment criteria for each application while also providing flexibility to potential new technology add-on payment applicants. As we stated in the proposed rule, at the same time, we also believe the significant ongoing concerns regarding antimicrobial resistance, and the need to help secure access to antibiotics for Medicare beneficiaries in a manner that is as expeditious as possible, may warrant additional flexibility with respect to applications for new technology add-on payments for certain antimicrobial products. Further, we noted that under the new alternative pathway for certain antimicrobial products, upon FDA marketing authorization, such products are considered new and not substantially similar to an existing technology and do not need to demonstrate substantial clinical improvement, resulting in a difference in the amount of information and time required for CMS to complete its evaluation as compared to technologies for which it must fully consider of all of the new medical service or technology add-on payment criteria. For these reasons, and for the reasons stated previously regarding the significant ongoing concerns related to the public health crisis represented by antimicrobial resistance, consistent with the Administration's commitment to address issues related to antimicrobial resistance, and to continue to help secure access to antibiotics and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible, we proposed a process by which a technology that meets the new technology add-on payment criteria under the alternative pathway for products designated as QIDPs or, as proposed and finalized, approved under FDA's LPAD pathway, would receive conditional approval for such payment even if the product has not been granted FDA marketing authorization by July 1 (the existing deadline by which any technology must be granted FDA marketing authorization in order to be eligible for a new technology add-on payment). (We note that for the remainder of this discussion, we refer to the alternative pathway at § 412.87(d), which, as finalized, will also include products approved under the LPAD pathway beginning with applications submitted for new technology add-on payments for FY 2022, as the ''alternative pathway for certain antimicrobial products'').

Under our proposal, a technology eligible for the new technology add-on payment alternative pathway for certain antimicrobial products would begin receiving the new technology add-on payment effective for discharges the quarter after FDA marketing authorization is granted. We proposed that the cutoff or deadline for this conditional approval would be FDA marketing authorization by July 1 of the fiscal year for which the applicant is applying for new technology add-on payments. We would consider July 1 to be the cutoff for conditional approval because under this proposal, if the FDA marketing authorization is received on or after July 1, the new technology add-on payment would not be effective for discharges until the beginning of the next quarter on October 1, which would be the start of the next fiscal year. For example, an eligible antimicrobial product is conditionally approved for the new technology add-on payment in the FY 2021 IPPS final rule. However, FDA marketing authorization is not granted until February 1, 2021. The new technology add-on payment for such an antimicrobial product would be made for discharges that use the technology on or after April 1, 2021 (the beginning of the quarter after the FDA marketing authorization was granted). Using the same example, if the eligible antimicrobial product received FDA marketing authorization on or after July 1, 2021, no new technology add-on payments would be made for FY 2021, because the beginning of the next quarter would be October 1, which is the beginning of FY 2022, the next fiscal year. As we discuss further, to be eligible for new technology add-on payments for FY 2022, the applicant would have needed to re-apply for such payments for FY 2022 by the applicable deadline.

In the FY 2009 IPPS final rule (73 FR 48562), we also stated that applications that receive FDA approval of the medical service or technology after July 1 would be able to reapply for the new medical service or technology add-on payment the following year (at which time they would be given full consideration in both the IPPS proposed and final rules). Consistent with this policy, an applicant for an eligible antimicrobial product that does not receive FDA marketing authorization during the conditional approval period described previously would need to evaluate whether it believes it is necessary to re-apply for new technology add-on payments for the following fiscal year. For example, an applicant for an eligible antimicrobial product for FY 2021 that receives conditional approval for FY 2021 (with a conditional approval period of on or after July 1, 2020 and before July 1, 2021) would still need to submit an application for FY 2022 in order to be eligible for new technology add-on payments in FY 2022. The applicant would need to evaluate whether it believes it is necessary to re-apply for new technology add-on payments for the next fiscal year based on when the applicant anticipates receiving FDA marketing authorization. However, we stated that we would encourage eligible antimicrobial product applicants to reapply for new technology add-on payments for the next fiscal year in case they do not receive FDA marketing authorization prior to July 1 of the fiscal year for which they initially applied. We also noted, as discussed previously, although FDA may provide advice on potential eligibility, FDA intends to make the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. As such, an applicant may not know with certainty at the time it applies for new technology add on payments under the alternative pathway for certain antimicrobial products whether it qualifies for that pathway. If the applicant drug ultimately does not receive approval under the LPAD pathway (but receives FDA approval otherwise) and is not designated as a QIDP, the applicant would not be eligible for approval under the

alternative pathway for certain antimicrobial products, and therefore, even if the product received conditional approval under this proposal, no new technology add-on payments would be made for that fiscal year. As described previously, the applicant would need to re-apply for new technology add on payments under the traditional pathway at § 412.87(b) for the following fiscal year if the applicant wishes to continue to seek approval for new technology add-on payments.

We proposed to revise § 412.87(e) to reflect this proposal by adding a new paragraph (3) which would provide for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We also proposed related revisions to the paragraph (e) introductory text and to paragraph (e)(2) to reflect this proposed new policy.

Comment: We received supportive comments for this proposal. According to these commenters, the proposal will be beneficial to manufacturers because it will prevent circumstances where products approved shortly after the fiscal year deadline have to wait until the next fiscal year to receive the new technology add-on payment. These commenters also noted that the drug development process does not always follow a consistent schedule and this change would ensure that all QIDP-designated antibiotics receive the same benefits upon approval.

Other commenters indicated the agency should consider establishing a subregulatory process to recognize products that qualify for a new technology add-on payment under the alternative pathway, rather than adopting the process for conditional approval described in the proposed rule. According to these commenters, providing conditional approval through an accelerated subregulatory process will allow alternative pathway products to rapidly receive new technology add-on payment designation after FDA approval and will maximize the new technology add-on payment eligibility period for those products. These commenters also stated that this access will be particularly important to drugs indicated for COVID–19 for which a new technology add-on payment application was most likely not submitted in the current year and that under the conditional approval process described in the proposed rule, could not receive new technology add-on payments until October 1, 2021 at the earliest.

In recommending a faster review process for medical devices that are part of FDA's Breakthrough Devices Program, commenters recommended that at a minimum, CMS should conduct a bi-annual review rather than the current annual review timeline. However, the commenters asserted that it is more appropriate that CMS instead review new technology add-on payment applications for medical devices that are part of FDA's Breakthrough Devices Program on the same quarterly timeline as it reviews traditional pass-through (TPT) applications for Breakthrough Designated technologies. The commenters acknowledged that although there would be increased burden on CMS associated with holding required public meetings and soliciting public comment for a more frequent review cycle, the need for earlier access to medical devices that are part of FDA's Breakthrough Devices Program outweighed considerations of administrative burden.

Similar to the comments received in response to the proposal to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway, many commenters requested expansion of the proposal to include conditional new technology add-on payment approval for products outside of the QIDP definition, but that have received fast track designation, breakthrough therapy designation, RMAT designation, are intended to treat a serious or life-threatening infection caused by a qualifying pathogen as listed in Section 505E(f) of the FD&C Act and include innovative non-antibiotic treatments for serious or life-threatening infections. Another commenter requested expansion of this proposal to generally include novel therapies that address an unmet medical need—a condition whose treatment or diagnosis is not addressed adequately by available therapy. According to this commenter, an unmet medical need includes an immediate need for a defined population (that is, to treat a serious condition with no or limited treatment) or a longer-term need for society (for example, to address the development of resistance to antibacterial drugs).

Finally, other commenters pointed to the justification CMS provided in the FY 2021 IPPS/LTCH PPS proposed rule for why certain antimicrobial products should receive conditional approval for NTAP, specifically the statement that, ''such products are considered new and not substantially similar to an existing technology and do not need to demonstrate substantial clinical improvement, resulting in a difference in the amount of information and time required for CMS to complete its evaluation as compared to technologies for which it must fully consider of all of the new medical service or technology add-on payment criteria.'' According to the commenters, this justification also applies to medical devices that are part of FDA's Breakthrough Devices Program. The commenters explained that while antimicrobial resistance is a critical need for the Medicare program, many products approved under FDA's Breakthrough Devices Program also fill critical needs for the Medicare population and may reduce administrative burden on CMS. According to the commenters, based on this justification, CMS should expand the proposed policy to provide for conditional new technology add-on payment approval for certain antimicrobial products that do not receive FDA marketing authorization by July 1 but otherwise meet the applicable add-on payment criteria to also include medical devices that are part of FDA's Breakthrough Devices Program that do not receive FDA marketing authorization by July 1 but otherwise meet the applicable add-on payment criteria.

Response: We appreciate the commenters' support for our proposal. We also appreciate the commenters' suggestions for other modifications to the new technology add-on payment policy, such as developing a more frequent approval process, which we will consider for future rulemaking.

In response to comments that requested expansion of the proposal to include conditional new technology add-on payment approval for products that fall outside of the QIDP definition, including products intended to treat a serious or life-threatening infection caused by a qualifying pathogen as listed in section 505E(f) of the FD&C Act, innovative non-antibiotic treatments for serious or life-threatening infections, novel therapies that address an unmet medical need and products that have received fast track designation, breakthrough therapy designation, or RMAT designation, as we discuss in section II.G.9.a. of this final rule with regard to our proposal to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved

under the LPAD pathway, we continue to recognize that the goal of facilitating access to new technologies for Medicare beneficiaries could also apply to other special designations. We will continue to consider this issue for future rulemaking. As we stated in the proposed rule and previously in this final rule, we believe that in order to address the significant ongoing concerns related to the public health crisis represented by antimicrobial resistance, consistent with the Administration's commitment to address issues related to antimicrobial resistance, and to continue to help secure access to antibiotics and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible, additional flexibility regarding new technology add-on payment applications for certain antimicrobial products is warranted and should be considered. We believe the alternative pathway for certain antimicrobials allows for this additional flexibility. Therefore, for the reasons discussed in this final rule, at this time we believe it would be appropriate to limit this proposed process for conditional approval to products designated as QIDPs or approved under FDA's LPAD pathway.

In response to the commenters that suggested expansion of the proposed policy to also include medical devices that are part of FDA's Breakthrough Devices Program that do not receive FDA marketing authorization by July 1 but otherwise meet the applicable add-on payment criteria, we agree that, as noted by the commenter, medical devices that are part of FDA's Breakthrough Device Program are evaluated under the alternative pathway for certain transformative new devices similar to how antimicrobial products are evaluated under the alternative pathway for certain antimicrobials with respect to the newness and substantial clinical improvement criteria. However, as we discussed in the proposed rule and in this final rule, in order to continue to help secure access to antibiotics and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible, we believe that additional flexibility is warranted with respect to the new technology payment applications for antimicrobial products to address the particular ongoing concerns relating to antimicrobial resistance. For these reasons, at this time we are not expanding our proposed process for conditional approval to include medical devices that are part of FDA's Breakthrough Devices Program that do not receive FDA marketing authorization by July 1 but otherwise meet the applicable add-on payment criteria. We may consider this further in the future as we gain more experience with this conditional approval process for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that does not receive FDA marketing authorization by the July 1 deadline.

After consideration of the comments received and for the reasons stated previously, we are finalizing our policy, as proposed, to establish a process by which a technology that meets the new technology add-on payment criteria under the alternative pathway for products designated as QIDPs or, as finalized in this final rule, approved under FDA's LPAD pathway, would receive conditional approval for such payment even if the product has not been granted FDA marketing authorization by July 1 but otherwise meets the applicable add-on payment criteria. Under this final policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

We received no comments on our proposed amendments to the regulations to reflect this policy. Therefore, we are finalizing our proposal to revise 412.87(e) by adding a new paragraph (3) which provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We are also finalizing our proposal to make related revisions to the paragraph (e) introductory text and to paragraph (e)(2) to reflect this new policy.

In addition, we proposed to make technical clarifications to the regulations in paragraph (e)(2) of § 412.87 by replacing the words ''FDA approval or clearance'' with ''FDA marketing authorization'' which conforms to the existing regulations in paragraphs (c)(1) and (d)(1) of § 412.87. We believe this more precisely describes the current policy and does not change or modify the policy set forth in existing § 412.87(e)(2). For example, under our current policy, in evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, we consider whether the technology has received marketing authorization by July 1 (such as Premarket Approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA)). Therefore, we believe the term ''marketing authorization'' would more precisely describe the various types of potential FDA approvals, clearances and classifications that we currently consider under our new technology add-on payment policy.

We received no comments on our proposal to make technical clarifications to the regulations in paragraph (e)(2) of § 412.87 by replacing the words ''FDA approval or clearance'' with ''FDA marketing authorization''. Therefore, we are finalizing as proposed.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2021 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050, which expires on March 31, 2022.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for

FY 2021 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2021 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we proposed to apply to the FY 2021 wage index appears under sections III.E.3. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2021 Hospital Wage Index

a. General

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some material modifications that have a number of downstream effects, such as reclassification changes (as discussed later in this preamble). CMS was unable to complete an extensive review and verification of the changes made by these bulletins until after the development of the FY 2020 IPPS/LTCH PPS proposed rule. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*. According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data.'' (We noted in the proposed rule that, on March 6, 2020, OMB issued OMB Bulletin 20–01 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*), but that it was not issued in time for development of the FY 2021 IPPS/LTCH PPS proposed rule.)

As noted previously and in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32967), while OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs would be split apart. In addition,

as we stated in the proposed rule, the revised OMB delineations would affect various hospital reclassifications, the out-migration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act. We discuss the revised OMB delineations and the effects of these revisions in this section of this rule. As previously noted, the March 6, 2020 OMB Bulletin 20–01 was not issued in time for development of the proposed rule. We stated in the proposed rule that we did not believe the updates included in OMB Bulletin 20–01 would impact the changes discussed in the proposed rule, and that if appropriate, we would propose any updates from this bulletin in the FY 2022 IPPS/LTCH PPS proposed rule.

b. Implementation of Revised Labor Market Area Delineations

We stated in the proposed rule (85 FR 32697) that we believe that using the revised delineations based on OMB Bulletin No. 18–04 will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, we proposed to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. We proposed to use these revised delineations to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies. Because of the previously described material changes, we also proposed a wage index transition applicable to hospitals that experience a significant decrease in their FY 2021 wage index compared to their final FY 2020 wage index. This transition is discussed in more detail in this section of this rule.

Comment: We received multiple comments supporting CMS's proposed adoption of the revised OMB delineations. MedPAC supported the adoption of the revised delineations in conjunction with the continuation of policies to reduce wage index disparities and mitigate the impact of changes to the wage index.

Several commenters opposed CMS's proposed implementation of the revised OMB delineations. Several commenters argued the CMS is not bound to adopt the revised delineations, and urged CMS to delay adoption of the revised delineations until the completion of the 2020 decennial census. Several comments specifically cited the lack of advance notice and the significant negative financial impacts to hospitals in several counties in the New York-Newark-Jersey City MSA resulting from the adoption of the revised delineations. These commenters cited past examples where CMS exercised discretion in modifying or delaying the implementation of OMB definitions and delineations in order to review and verify the impacts and ramifications. For instance, the revised delineations posted in February of 2012 (OMB Bulletin No: 13–01) were not adopted by CMS until FY 2015. One commenter presented the following considerations they consider compelling reasons for CMS to alter or postpone the adoption of the revised delineations. First, the commenter cites the effect of the COVID–19 pandemic, which has caused extraordinary increases in costs and revenue losses, particularly for hospitals in this New York-Newark-Jersey City, NY-NY MSA. The commenter contends that, given the timing of when the FY 2021 IPPS/LTCH proposed rule was in development, the proposed policies could not have fully considered the effect of the crisis. Second, the commenter contends that adopting the proposed delineation changes is inconsistent with prior agency action because, as referenced by the agency in the proposed rule, CMS has typically only made minor changes to delineations between decennial census periods. The commenter stated that it is unprecedented for CMS to establish a new CBSA (the New Brunswick-Lakewood, NJ CBSA) based on OMB's delineation of a new Metropolitan Division outside of a decennial census. The commenter contends that OMB Bulletin 18–04 warned that comparing Metropolitan Divisions with entire MSAs would be inappropriate and further contend that neither CMS, nor OMB, have presented any evidence that the counties that constitute the New Brunswick-Lakewood, NJ CBSA function as a distinct area within the larger New York-Newark-Jersey City, NY-NJ MSA. Third, the commenter contends that while CMS cites an increase in the integrity of the IPPS wage index system as a rationale for implementing the revised OMB delineations, CMS has neither provided an explanation as to the integrity shortcomings within the current delineations, nor how they would be corrected by implementing the new delineations. The commenter highlights OMB's statement in Bulletin 18–04 instructing any agency using these delineations to seek public comment on their proposed use. They further explain that the New Brunswick-Lakewood Metropolitan Division was created because an OMB commuting threshold between Monmouth and Middlesex Counties was narrowly exceeded, meeting the criteria for Middlesex, Monmouth, and Ocean Counties to be deemed a separate division within the larger New York-Newark-Jersey City MSA, leading to their fourth point that the underlying commuting data used to create the delineations is fundamentally flawed. They specifically cite the effects of Superstorm Sandy, which came ashore in New York and New Jersey in late October of 2012 and caused many months of severe disruption to the area. Since the commuting patterns data utilized by OMB were based on the 2011–2015 5-Year ACS Commuting Flows dataset, the commenter states it is unreasonable to assume that Superstorm Sandy did not affect the commute-to-work data that OMB used to create Bulletin No. 18–04. Given this event, they believe relying on the commuting data used by OMB actually distorts the integrity of wage index system, rather than improving it.

Given these considerations discussed by this commenter and generally cited by several additional commenters, commenters urged CMS to delay implementation of the revised OMB delineations. Commenters warned that the adoption would create a ''downward spiral'' effect when hospitals may not have sufficient Medicare payments to meet future wage costs. One commenter specifically cited CMS's FY 2020 wage index ''compression'' policy as an additional financial challenge placed on hospitals the New York City metropolitan area, which will only be compounded through adopting the revised delineations. Another commenter stated, that while some affected hospitals may be eligible to obtain MGCRB reclassifications as early as FY 2022, the negative financial impacts for hospitals unable to reclassify would only further create competitive inequalities between hospitals within the same labor market area. Additional commenters urged CMS to engage further with stakeholders to develop a more comprehensive wage index reform to address the disparities that exist within the current wage index system.

Response: We appreciate the comments supporting adoption of the revised OMB delineations, including the supportive comment from MedPAC, and refer commenters to section III.G.3 of this final rule for additional discussion of the continuation of the policies CMS finalized in the FY 2020 IPPS/LTCH PPS final rule to reduce wage index

disparities, including the low wage index hospital policy. In response to commenters who urged CMS to engage further with stakeholders to develop a more comprehensive wage index reform to address wage index disparities, we appreciate the continued interest in wage index reform. We note that, as a first step toward comprehensive wage index reform, the FY 2021 President's Budget proposes the Secretary conduct and report on a demonstration to improve the Medicare inpatient hospital wage index.

We have closely reviewed all the comments received. While we understand implementing revisions to labor market area delineations may have either positive or negative effects on payment rates for some hospitals, we believe it is important for the IPPS to use the updated labor market area delineations in order to maintain a more accurate and up-to date payment system that reflects the reality of current labor market conditions. We believe that the updated OMB delineations increase the integrity of the IPPS wage index by creating a more accurate, updated representation of variations in area wage levels as compared to the current OMB delineations. In particular, while the revised delineations do not reflect the results of a new decennial census, they do incorporate the results from updated commuting survey data, the 2011–2015 American Commuting Survey (ACS). As such, we believe that the revised OMB delineations would help ensure more accurate and appropriate payments as compared to the current OMB delineations. We concur with commenters that CMS is not bound by statute to adhere to OMB definitions or delineations in calculating the IPPS wage index. However, because we believe we have broad authority under section 1886(d)(3)(E) of the Act to determine the labor market areas used for the IPPS wage index, and because we believe the updated delineations reflected in OMB Bulletin No. 18–04 better reflect the local economies and wage levels of the areas in which hospitals are currently located, we believe it is appropriate to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, for the IPPS wage index effective beginning in FY 2021. In response to commenters who stated that we have in the past delayed implementation of revised delineations in order to better evaluate their impacts on the IPPS wage index, we note that we have reviewed our findings and impacts relating to the revised OMB delineations set forth in OMB Bulletin No. 18–04, and for the reasons discussed above, we find no compelling reason to further delay implementation. Furthermore, as explained in section III.A.2.c of this final rule, we are implementing a wage index transition for FY 2021 under which we will apply a 5 percent cap on any decrease in a hospital's wage index compared to its wage index for FY 2020 to mitigate significant negative impacts of, and provide time for hospitals to adapt to, the revised OMB delineations. We believe that the transition described in Section III.A.2.c will provide negatively affected hospitals the necessary time to adjust and explore newly available reclassification options (please note, we address comments regarding this proposed transition in section III.A.2.c). Thus, for these reasons, we do not believe it is necessary or appropriate to delay or alter implementation of the revised delineations.

With regard to the comments that would seek a delay in adopting the revised delineations given the effects of the COVID–19 related public health emergency, because the revised OMB delineations would help ensure more accurate payments than under the current OMB delineations, we believe it is important to adopt the revised delineations as soon as possible. Nothing about the COVID–19 related public health emergency would diminish the importance of ensuring that payments are as accurate as possible. In addition, we note that CMS has taken unprecedented steps to provide the healthcare community, including hospitals, with flexibilities and support to respond to the COVID–19 public health emergency (for example, see *https://www.cms.gov/files/document/covid-accomplishments.pdf*). While we continue our critical work in this area, for the reasons discussed previously, we believe it is appropriate to implement the updated OMB delineations effective beginning in FY 2021.

In response to the comment that contends that adopting the revised delineations would be inconsistent with prior agency action because CMS has typically only made minor changes to labor market areas between decennial censuses, we note that CMS has routinely adopted revised delineations issued by OMB between decennial censuses (for example, the revised delineations issued in OMB Bulletin Nos. 15–01 and 17–01). Thus, consistent with past agency practice, we proposed to adopt the revised delineations in OMB Bulletin No. 18–04. As stated in the proposed rule (85 FR 32696 through 32697), we acknowledge that the changes outlined in OMB Bulletin No. 18–04 are more significant than typical OMB delineation revisions issued between decennial censuses; however, the overall impacts of these revised delineations are still more limited in scope than revisions that accompany the release of decennial censuses. In addition, as we discuss earlier, we believe that the updated OMB delineations increase the integrity and accuracy of the IPPS wage index by creating a more accurate, updated representation of variations in area wage levels as compared to the current OMB delineations.

In response to commenters that contend that CMS should not establish a new CBSA based on OMB's delineation of a new Metropolitan Division between decennial census results and that comparing Metropolitan Divisions with entire MSAs would be inappropriate, we acknowledge that when OMB implemented the Statistical Area Definitions, including the ''Metropolitan Division'' definitions, OMB included guidance in Bulletin 04–02 and subsequent updates that these delineations should be evaluated by any Agency before use in program funding formulas. As we stated in the FY 2005 IPPS/LTCH final rule (69 FR 49027), while we recognize that CBSA-based delineations were not specifically designed to define labor market areas, we believe they do serve as useful proxies for this purpose. In that rule (69 FR 49029), we further articulated our finding that Metropolitan Divisions of MSAs most closely resembled the labor market configuration of the previous OMB ''Primary Metropolitan Statistical Areas'' delineations. That is, by treating Metropolitan Divisions of MSAs as separate labor market areas, the resulting configuration in FY 2005 would more closely resemble the labor market map in place prior to FY 2005. Therefore, we finalized our current policy to treat Metropolitan Divisions of MSAs as separate labor market areas when calculating wage index values. For sake of consistency, it has been CMS's longstanding practice to refer to Metropolitan Divisions, undivided MSAs, and State's rural area as CBSAs. Because, as discussed above, we believe that OMB's Statistical Area Definitions, including Metropolitan Division definitions, serve as useful proxies in defining labor market areas for purposes of the IPPS wage index, and that the revised OMB delineations, including Metropolitan Division delineations, based on updated commuting data create a more accurate representation of variations in area wage levels, and given

our long history of adopting updated OMB revisions to Metropolitan Division delineations, and our consistent treatment of Metropolitan Divisions as separate labor market areas, we believe it is appropriate to adopt the revised delineations in OMB Bulletin No. 18–04, including the revised Metropolitan Division definitions, beginning with the FY 2021 wage index.

We note that the configuration of the New York-Newark-Jersey City MSA in 2005 (then titled New York-Northern New Jersey, Long Island) consisted of 5 metropolitan divisions. Broadly speaking, the divisions consisted of a New York City division (New York-White Plains-Wayne), a Long Island division (Nassau-Suffolk), a Mid-Hudson NY division (Poughkeepsie-Newburgh-Middletown), a North-Central, NJ division (Newark-Union), and a Central NJ-NJ Shore division (Edison). These delineations remained in effect until FY 2015 when CMS adopted revised delineations based OMB Bulletin No.13–01 (published February 28, 2013). This bulletin eliminated the Edison, NJ division, moving 3 of its 4 counties to the New York City division, and one to the North-Central, NJ division. Also in this bulletin, Orange County, NY (in the New York City division) and Putnam County, NY (in the Mid-Hudson division) swapped division assignments. Under the revised delineations in OMB Bulletin No. 18–04, the changes adopted in FY 2015 to the New York-Newark-Jersey City MSA have reverted back to the CBSA delineations in place from FY 2005 through FY 2014. The 4 counties of the former Edison, NJ metropolitan division are again joined together in the New Brunswick-Lakewood, NJ metropolitan division, and Orange and Putnam County, NY once again swapped division assignment. We note that, prior to FY 2005, CMS used OMB ''Primary Metropolitan Statistical Areas'' delineations (OMB Bulletin 95–04) to define labor market areas. Under those delineations, none of the 4 counties of the Edison, NJ/New Brunswick-Lakewood, NJ metropolitan division nor Orange County, NY were considered part the same labor market area as any county in the New York City labor market. Per OMB definitions, it is true that relatively small deviations in commuting interchange statistics may cause some counties to move between CBSAs if they are close to a specific threshold definition; however, we believe that including such changes in defining labor market areas would allow the wage index to more accurately reflect variations in area wage levels. Based upon our analysis of the 2011–2015 5-Year ACS Commuting Flows and Employment dataset and the 2010 OMB Standards for Delineating Metropolitan and Micropolitan Statistical Areas (75 FR 37249–37252), the New Brunswick-Lakewood, NJ metropolitan division was created from the larger New York-Newark-Jersey City NY-NJ MSA because two contiguous ''secondary counties'' (Middlesex County and Monmouth County) had an Employment Interchange Measure (EIM) greater than 15. The EIM, as defined by OMB (75 FR 37251), between these two counties was 14.8 based of the previous 2006–2010 ACS Commuting Flow dataset, and therefore did not qualify as a separate metropolitan division. In the updated 2011–2015 commuting dataset, the EIM between these two counties is 16.1. While the commenters claimed the 2011–2015 dataset results in these counties only narrowly meeting the threshold to be defined as a separate metropolitan division, because the EIM (16.1) based on the updated commuting dataset does clearly exceed the threshold, we believe it is appropriate to take this into account in updating the labor market area delineations. We note that the EIM measure of 14.8 based on the older 2006–2010 commuting dataset was far closer to the threshold. We are not convinced that the proposed delineation changes are unwarranted or that there is evidence of any distortion or exceptional statistical anomaly, such as the impacts of Superstorm Sandy, as suggested by commenters. In fact, by comparing the most recent combined three year average hourly wages for all hospitals in the counties being removed from the New York-Jersey City-White Plains, NY-NJ CBSA ($47.79) to the hospitals remaining in the proposed New York City-Jersey City-White Plains, NY-NJ CBSA ($59.21), it is evident that labor costs are significantly lower for most hospitals in the counties removed from the CBSA.

As far as comments regarding the lack of notice provided to hospitals regarding the proposed adoption of the revised delineations, we note that the delineation files produced by OMB have been public for nearly 2 years, and OMB definitions and criteria are subject to separate notice and comment rulemaking. In the past, we have delayed implementation of delineations in order to fully evaluate their impacts on IPPS wage index values, and as previously discussed, we have fully assessed the impacts of the revised delineations in OMB Bulletin No. 18–04. As discussed previously, we believe it would be appropriate to adopt the revised delineations to reflect a more accurate, updated representation of variations in area wage levels as compared to the current OMB delineations.

After consideration of the public comments we received, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed implementation of the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index.

i. Micropolitan Statistical Areas

As discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), OMB defines a ''Micropolitan Statistical Area'' as a CBSA ''associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000'' (75 FR 37252). We refer to these areas as Micropolitan Areas. Since FY 2005, we have treated Micropolitan Areas as rural and include hospitals located in Micropolitan Areas in each State's rural wage index. We refer the reader to the FY 2005 IPPS final rule (69 FR 49029 through 19032) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49952) for a complete discussion regarding this policy and our rationale for treating Micropolitan Areas as rural. We stated in the proposed rule (85 FR 32967) that, for the reasons discussed in the FY 2005 IPPS final rule and in the FY 2015 IPPS final rule, we believed that the best course of action would be to continue this policy and include hospitals located in Micropolitan Areas in each State's rural wage index. Therefore, in conjunction with our proposal to implement the new OMB statistical area delineations beginning in FY 2021, we proposed to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index. We did not receive any comments specific to this proposal, and therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification, to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

ii. Urban Counties That Would Become Rural Under the Revised OMB Delineations

As previously discussed, we proposed to implement the revised OMB statistical area delineations (based upon

OMB Bulletin No. 18–04) beginning in FY 2021. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32697), we stated that our analysis shows that a total of 34 counties (and county equivalents) and 10 hospitals that were once considered part of an urban CBSA would be considered to be located in a rural area, beginning in FY 2021, under these revised OMB delineations. In the proposed rule (85 FR 32698 through 32699), we included the following chart listing the 34 urban counties that would be rural if we finalized our proposal to implement the revised OMB delineations.

FIPS County Code	County/County Equivalent	State	Current CBSA Code	Current CBSA Name
01127	WALKER	AL	13820	Birmingham-Hoover, AL
12045	GULF	FL	37460	Panama City, FL
13007	BAKER	GA	10500	Albany, GA
13235	PULASKI	GA	47580	Warner Robins, GA
15005	KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI
17039	DE WITT	IL	14010	Bloomington, IL
17053	FORD	IL	16580	Champaign-Urbana, IL
18143	SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
18179	WELLS	IN	23060	Fort Wayne, IN
19149	PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
20095	KINGMAN	KS	48620	Wichita, KS
21223	TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
22119	WEBSTER	LA	43340	Shreveport-Bossier City, LA
26015	BARRY	MI	24340	Grand Rapids-Wyoming, MI
26159	VAN BUREN	MI	28020	Kalamazoo-Portage, MI
27143	SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
28009	BENTON	MS	32820	Memphis, TN-MS-AR
29119	MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
30037	GOLDEN VALLEY	MT	13740	Billings, MT
31081	HAMILTON	NE	24260	Grand Island, NE
38085	SIOUX	ND	13900	Bismarck, ND
40079	LE FLORE	OK	22900	Fort Smith, AR-OK
45087	UNION	SC	43900	Spartanburg, SC
46033	CUSTER	SD	39660	Rapid City, SD
47081	HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	ARANSAS	TX	18580	Corpus Christi, TX
48221	HOOD	TX	23104	Fort Worth-Arlington, TX
48351	NEWTON	TX	13140	Beaumont-Port Arthur, TX
48425	SOMERVELL	TX	23104	Fort Worth-Arlington, TX
51029	BUCKINGHAM	VA	16820	Charlottesville, VA
51033	CAROLINE	VA	40060	Richmond, VA
51063	FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
53013	COLUMBIA	WA	47460	Walla Walla, WA
53051	PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA

We proposed that the wage data for all hospitals located in the counties listed in this chart would now be considered rural when calculating their respective State's rural wage index. We stated in the proposed rule (85 FR 32699) that we recognize that rural areas typically have lower area wage index values than urban areas, and hospitals located in these counties may experience a negative impact in their IPPS payment due to the adoption of the revised OMB delineations. We referred readers to our discussion of our proposed wage index transition policy to apply a 5 percent cap in FY 2021 for hospitals that may experience any decrease in their final wage index from the prior fiscal year. We also referred readers to the discussion of our proposed revisions to the list of counties deemed urban under section 1886(d)(8)(B) of the Act that would affect the hospitals located in these proposed rural counties.

In addition, we noted in the proposed rule that the provisions of § 412.102 of the regulations would continue to apply with respect to determining DSH payments. Specifically, we stated that in the first year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals two-thirds of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals one third of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural.

We did not receive any comments specific to the proposed list of counties that would become rural under the revised OMB delineations. Thus, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed reassignment of the 34 counties set forth in the chart from urban areas to rural areas for purposes of the IPPS wage index based on the revised OMB delineations in OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index.

iii. Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we proposed to implement the revised OMB statistical area delineations (based upon OMB Bulletin No. 18–04) beginning in FY 2021. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32699), we indicated that analysis of these OMB statistical area delineations shows that a total of 47 counties (and county equivalents) and 17 hospitals that were located in rural areas would be located in urban areas under the revised OMB delineations. In the proposed rule, we included the following chart listing the 47 rural counties that would be urban if we finalized our proposal to implement the revised OMB delineations.

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COUNTIES THAT WOULD GAIN URBAN STATUS

FIPS County Code	County/County Equivalent	State	CBSA Code	CBSA Name
01063	GREENE	AL	46220	Tuscaloosa, AL
01129	WASHINGTON	AL	33660	Mobile, AL
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
12075	LEVY	FL	23540	Gainesville, FL
13259	STEWART	GA	17980	Columbus, GA-AL
13263	TALBOT	GA	17980	Columbus, GA-AL
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
18047	FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
18121	PARKE	IN	45460	Terre Haute, IN
18171	WARREN	IN	29200	Lafayette-West Lafayette, IN
19015	BOONE	IA	11180	Ames, IA
19099	JASPER	IA	19780	Des Moines-West Des Moines, IA
20061	GEARY	KS	31740	Manhattan, KS
21043	CARTER	KY	26580	Huntington-Ashland, WV-KY-OH
22007	ASSUMPTION	LA	12940	Baton Rouge, LA
22067	MOREHOUSE	LA	33740	Monroe, LA
25011	FRANKLIN	MA	44140	Springfield, MA
26067	IONIA	MI	24340	Grand Rapids-Kentwood, MI
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
28051	HOLMES	MS	27140	Jackson, MS
28131	STONE	MS	25060	Gulfport-Biloxi, MS
29053	COOPER	MO	17860	Columbia, MO
29089	HOWARD	MO	17860	Columbia, MO
30095	STILLWATER	MT	13740	Billings, MT
37007	ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
37029	CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
39123	OTTAWA	OH	45780	Toledo, OH
45027	CLARENDON	SC	44940	Sumter, SC
47053	GIBSON	TN	27180	Jackson, TN
47161	STEWART	TN	17300	Clarksville, TN-KY
48203	HARRISON	TX	30980	Longview, TX
48431	STERLING	TX	41660	San Angelo, TX
51097	KING AND QUEEN	VA	40060	Richmond, VA
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54065	MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR

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We proposed that when calculating the area wage index, the wage data for hospitals located in these counties would be included in their new respective urban CBSAs. We stated in the proposed rule (85 FR 32701) that, typically, hospitals located in an urban area would receive a wage index value higher than or equal to hospitals located

in their State's rural area. We referred readers to our discussion of our proposed wage index transition policy to apply a 5 percent cap in FY 2021 for hospitals that may experience any decrease in their final wage index from the prior fiscal year.

In the proposed rule, we also noted that due to the adoption of the revised OMB delineations, some CAHs that were previously located in rural areas may be located in urban areas. The regulations at §§ 412.103(a)(6) and 485.610(b)(5) provide affected CAHs with a two-year transition period that begins from the date the redesignation becomes effective. We stated that the affected CAHs must reclassify as rural during this transition period in order to retain their CAH status after the two-year transition period ends. We referred readers to the FY 2015 IPPS/LTCH final rule (79 FR 50162 and 50163) for further discussion of the two-year transition period for CAHs.

Comment: We received a comment regarding a hospital in Harnett County, NC. Harnett County is a rural county under the current OMB delineations. Under the ''Lugar'' policy at section 1886(d)(8)(B) of the Act, all hospitals in the county are currently deemed to be reclassified as urban to Raleigh, NC (CBSA 39580). Under the revised OMB delineations, Harnett County would be considered urban, part of Fayetteville, NC (CBSA 22180). The commenters stated that this change in status will have a significant financial impact on the hospital. The commenter questions how the county-based commuting patterns, which supported the county's continued Lugar status in the FY 2019 IPPS/LTCH proposed rule, could have changed in such a manner that Harnett is now considered an outlying county of the Fayetteville, NC CBSA. The commenter requested CMS reconsider the placement of Harnett County, NC in the Fayetteville, NC CBSA, believing the data included in the upcoming 2020 decennial census would appropriately place Harnett County in the Raleigh-Cary, NC CBSA.

Response: As the commenter recognizes, based on the updated OMB delineations in OMB Bulletin No. 18–04, Harnett County is considered urban, part of Fayetteville, NC (CBSA 22180). In OMB Bulletin No. 18–04, OMB is using an updated commuting data set to determine statistical area delineations, specifically the 2011–2015 5-Year ACS Commuting Flows and Employment, which is available on the internet at *https://www.census.gov/topics/employment/commuting/guidance/flows.html.* As discussed earlier, we believe the updated OMB delineations in OMB Bulletin No. 18–04, which are based on this updated commuting data, provide a more updated and accurate representation of variations in area wage levels. As such, we believe that adoption of the revised OMB delineations would increase the integrity of the IPPS wage index and help ensure more accurate and appropriate payments as compared to the current OMB delineations. Under section 1886(d)(8)(B) of the Act, only hospitals located in rural counties (that meet the criteria in section 1886(d)(8)(b)) can be designated as ''Lugar'' hospitals. Since Harnett County, NC would be considered an urban county located in the Fayetteville, NC CBSA under the updated OMB delineations, hospitals located in Harnett County would no longer be considered ''Lugar'' hospitals under section 1886(d)(8)(b) of the Act and would no longer be considered reclassified under that statute to the Raleigh-Cary, NC (CBSA 39580). Based on the updated delineations in OMB Bulletin No. 18–04, we believe that Harnett County is appropriately classified as urban, part of the Fayetteville, NC CBSA; however, we may consider proposing future revisions to the county's geographic classification if warranted based on future updates to the OMB delineations.

Comment: One commenter requested CMS consider a 2-year extension of rural status for Medicare Dependent Hospitals (MDH) and Sole Community Hospitals (SCH) located in counties that are gaining urban status. Since SCH and MDH statuses are dependent upon a hospital being considered rural, the commenter states they should be allotted additional time to obtain a rural status. The commenter suggested CMS adopt a similar transition period policy for SCHs and MDHs as what is granted to Critical Access Hospitals at § 412.103(a)(6).

Response: We appreciate these comments. However, we do not believe it would be appropriate to extend rural status for MDHs and SCHs for a period of time after implementation of the revised OMB delineations to provide additional time to obtain rural reclassification through § 412.103. As discussed in the FY 2015 IPPS/LTCH final rule (79 FR 49983), we believe the payment consequences for CAHs of losing rural status are generally greater than for other provider types. In addition, given the different Conditions of Participation (CoPs) for CAHs, and that it would be generally more difficult for a CAH to have to meet the hospital CoPs instead of the CAH CoPs, only a CAH also faces the potential loss of its ability to continue to participate in the Medicare and Medicaid programs if such rural status is lost. We believe that the combination of the generally greater payment consequences for CAHs relative to other provider types combined with the unique consequences for CAHs with respect to the CoPs make it appropriate for CAHs to be afforded a 2-year transition period in which to reclassify not afforded to other provider types. Furthermore, of the 17 hospitals located in newly urban counties, fewer than half appear to have either SCH or MDH status. We believe all could readily obtain rural reclassification under the current criteria in § 412.103 in order to retain their status as MDHs and SCHs. We remind hospitals that § 412.103 reclassification requests are effective as of the date of application. If the application is filed with the appropriate regional office by October 1, 2020, when approved, the hospital would experience no gap in rural status. We believe that the relatively few SCHs and MDHs affected by the revised delineations will have adequate time to submit a complete application. Therefore, for the reasons explained above, we are not modifying existing regulations to extend rural status for MDHs and SCHs for a period of time after implementation of the revised OMB delineations.

After consideration of the public comments we received, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed reassignment of the 47 counties (and county equivalents) listed in the chart from rural areas to urban areas for purposes of the IPPS wage index based on the revised OMB delineations in OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index.

iv. Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

As we stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32702), in addition to rural counties becoming urban and urban counties becoming rural, some urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the new OMB delineations. We stated that, in other cases, adopting the revised OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, we noted that CBSA 19380 (Dayton, OH) would experience both a change to its number

and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. In the proposed rule (85 FR 32703 through 32704), we provided the following list of such CBSAs where we proposed to change the name and/or CBSA number only.

URBAN AREAS WITH CBSA NAME AND/OR NUMBER CHANGE

Current CBSA Code	Current CBSA Name	CBSA Code	CBSA Name
10540	Albany, OR	10540	Albany-Lebanon, OR
11500	Anniston-Oxford-Jacksonville, AL	11500	Anniston-Oxford, AL
12060	Atlanta-Sandy Springs-Roswell, GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
12420	Austin-Round Rock, TX	12420	Austin-Round Rock-Georgetown, TX
13460	Bend-Redmond, OR	13460	Bend, OR
13980	Blacksburg-Christiansburg-Radford, VA	13980	Blacksburg-Christiansburg, VA
14740	Bremerton-Silverdale, WA	14740	Bremerton-Silverdale-Port Orchard, WA
15380	Buffalo-Cheektowaga-Niagara Falls, NY	15380	Buffalo-Cheektowaga, NY
19380	Dayton, OH	19430	Dayton-Kettering, OH
24340	Grand Rapids-Wyoming, MI	24340	Grand Rapids-Kentwood, MI
24860	Greenville-Anderson-Mauldin, SC	24860	Greenville-Anderson, SC
25060	Gulfport-Biloxi-Pascagoula, MS	25060	Gulfport-Biloxi, MS
25540	Hartford-West Hartford-East Hartford, CT	25540	Hartford-East Hartford-Middletown, CT
25940	Hilton Head Island-Bluffton-Beaufort, SC	25940	Hilton Head Island-Bluffton, SC
28700	Kingsport-Bristol-Bristol, TN-VA	28700	Kingsport-Bristol, TN-VA
31860	Mankato-North Mankato, MN	31860	Mankato, MN
33340	Milwaukee-Waukesha-West Allis, WI	33340	Milwaukee-Waukesha, WI
34940	Naples-Immokalee-Marco Island, FL	34940	Naples-Marco Island, FL
35660	Niles-Benton Harbor, MI	35660	Niles, MI
36084	Oakland-Hayward-Berkeley, CA	36084	Oakland-Berkeley-Livermore, CA
36500	Olympia-Tumwater, WA	36500	Olympia-Lacey-Tumwater, WA
38060	Phoenix-Mesa-Scottsdale, AZ	38060	Phoenix-Mesa-Chandler, AZ
39140	Prescott, AZ	39150	Prescott Valley-Prescott, AZ
43524	Silver Spring-Frederick-Rockville, MD	23224	Frederick-Gaithersburg-Rockville, MD
44420	Staunton-Waynesboro, VA	44420	Staunton, VA
44700	Stockton-Lodi, CA	44700	Stockton, CA
45940	Trenton, NJ	45940	Trenton-Princeton, NJ
46700	Vallejo-Fairfield, CA	46700	Vallejo, CA
47300	Visalia-Porterville, CA	47300	Visalia, CA
48140	Wausau, WI	48140	Wausau-Weston, WI
48424	West Palm Beach-Boca Raton-Delray Beach, FL	48424	West Palm Beach-Boca Raton-Boynton Beach, FL

In the proposed rule, we did not further discuss these changes because we stated that they were inconsequential changes with respect to the IPPS wage index. However, we stated that in other cases, if we adopted the revised OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. For example, we noted that Kendall County, IL would be moved from the current CBSA 16974 (Chicago-Naperville-Arlington Height, IL) into CBSA 20994 (Elgin, IL). We further noted that the remaining counties in the current CBSA 16974 would be assigned to the CBSA 16984 (Chicago-Naperville-Evanston, IL). The constituent counties of CBSA 16974 would therefore be split into two different urban CBSAs. We also stated that there would be a significant rearrangement in the constituent counties among the New York City Area Metropolitan Divisions. Most notably, Monmouth, Middlesex, and Ocean Counties in NJ would move from the current CBSA 35614 (New York-Jersey City-White Plains, NY-NJ) to the CBSA 35154 (New Brunswick-Lakewood, NJ). Also, Somerset County, NJ would move from current CBSA 35084 (Newark, NJ-PA) to CBSA 35154. In the proposed rule, we included the following chart listing the urban counties that would move from one urban CBSA to a new or modified CBSA if we adopted the revised OMB delineations.

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COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA

FIPS County Code	County/County Equivalent	State	Current CBSA Code	Current CBSA Name	CBSA Code	CBSA Name
17031	COOK	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17043	DU PAGE	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17063	GRUNDY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17093	KENDALL	IL	16974	Chicago-Naperville-Arlington Heights, IL	20994	Elgin, IL
17111	MC HENRY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17197	WILL	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
34023	MIDDLESEX	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34025	MONMOUTH	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34029	OCEAN	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34035	SOMERSET	NJ	35084	Newark, NJ-PA	35154	New Brunswick-Lakewood, NJ
36027	DUTCHESS	NY	20524	Dutchess County-Putnam County, NY	39100	Poughkeepsie-Newburgh-Middletown, NY
36071	ORANGE	NY	35614	New York-Jersey City-White Plains, NY-NJ	39100	Poughkeepsie-Newburgh-Middletown, NY
36079	PUTNAM	NY	20524	Dutchess County-Putnam County, NY	35614	New York-Jersey City-White Plains, NY-NJ
47057	GRAINGER	TN	28940	Knoxville, TN	34100	Morristown, TN
54043	LINCOLN	WV	26580	Huntington-Ashland, WV-KY-OH	16620	Charleston, WV
72055	GUANICA	PR	38660	Ponce, PR	49500	Yauco, PR
72059	GUAYANILLA	PR	38660	Ponce, PR	49500	Yauco, PR
72111	PENUELAS	PR	38660	Ponce, PR	49500	Yauco, PR
72153	YAUCO	PR	38660	Ponce, PR	49500	Yauco, PR

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In the proposed rule (85 FR 32705), we stated that if hospitals located in these counties move from one CBSA to another under the revised OMB

delineations, there may be impacts, both negative and positive, upon their specific wage index values. We referred readers to our discussion of our proposed wage index transition policy to apply a 5 percent cap in FY 2021 for hospitals that may experience any decrease in their final wage index from the prior fiscal year. We also referred readers to our discussion of our proposals to reassign MGCRB wage index reclassifications for hospitals currently assigned to these modified CBSAs.

We did not receive any comments on the CBSAs that would undergo a change in name and/or CBSA number only. The comments we received regarding the list of urban counties that would move from one urban CBSA to a new or modified CBSA are discussed in section III.I.2.c.(1) of this final rule. As discussed in that section, we are finalizing, without modification, our proposal to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index. After consideration of the public comments we received, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed list of CBSAs that would move from one urban CBSA to a new or modified CBSA for purposes of the IPPS wage index based on the revised OMB delineations in OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index.

c. Transition for Hospitals Negatively Impacted

We stated in the proposed rule (85 FR 32706) that, overall, we believe implementing the revised OMB statistical area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognized that some hospitals would experience decreases in wage index values as a result of our implementation of the revised labor market area delineations. We also stated that we realize that some hospitals would have higher wage index values due to our implementation of the new labor market area delineations.

In the past, we have proposed and finalized budget neutral transition policies to help mitigate negative impacts on hospitals of certain wage index proposals. For example, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49960 through 49963) when we implemented new OMB delineations based on the 2010 decennial census data, we finalized budget neutral transitions for certain situations. Specifically, in the FY 2015 IPPS/LTCH PPS final rule, for a period of 3 fiscal years, we allowed urban hospitals that became rural under the new delineations (and that had no form of wage index reclassification or redesignation) to maintain the wage index value of the CBSA in which they were physically located for FY 2014; and for hospitals that experienced a decrease in wage index values due to the change in labor market area definitions, we implemented a 1-year blended wage index where hospitals received 50 percent of their wage index based on the new OMB delineations that went into effect in FY 2015, and 50 percent of their wage index based on their FY 2014 labor market area. As we stated in the proposed rule, this blended wage index required us to calculate wage indexes for all hospitals using both old and new labor market definitions even though it only applied to hospitals that experienced a decrease in wage index values due to a change in labor market area definitions. More recently, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42336 through 42338), we finalized a wage index transition to help mitigate any significant decreases in the wage index values of hospitals compared to their final wage index value from the prior fiscal year due to the combined effect of the changes to the FY 2020 wage index. Specifically, for FY 2020, we implemented a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019.

As previously mentioned in this final rule and in the proposed rule (85 FR 32706), while the revised OMB delineations in OMB Bulletin 18–04 are not based on new census data, there were some material changes in the OMB delineations. Also, as previously mentioned, the revisions in this OMB bulletin are updates to the CBSA delineations already adopted in FY 2015 based on the 2010 census data. For these reasons, we stated in the proposed rule that, for FY 2021, we do not believe it is necessary to implement the multifaceted transitions we established in FY 2015 for the adoption of the new OMB delineations based on the new decennial census data. However, in accordance with our past practice of implementing transition policies to help mitigate negative impacts on hospitals of certain wage index proposals, we stated in the proposed rule that if we adopt the revised OMB delineations, we believe it would be appropriate to implement a transition policy since, as previously mentioned, some of these revisions are material, and may negatively impact payments to hospitals. For example, we explained that changes in the county makeup of a CBSA, by adding or removing a constituent county, may change the pool of hospitals contributing average hourly wage data, potentially resulting in lower wage index values for certain areas. We noted that when CMS implemented various changes to the hospital wage index in prior rulemaking, commenters frequently supported transition policies that ensured wage index values maintain a degree of year-to-year consistency (see comments to our FY 2015 IPPS/LTCH PPS final rule transition policies at 79 FR 49959 through 49961). Thus, we stated in the proposed rule that we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year, as we did for FY 2020, would be an appropriate transition for FY 2021 for the revised OMB delineations as it provides predictability in payment levels from FY 2020 to the upcoming FY 2021. We stated that the FY 2021 5-percent cap on wage index decreases would be applied to all hospitals that have any decrease in their wage indexes, mitigating significant negative decrease in wage index values. Given the significant portion of Medicare IPPS payments that are adjusted by the wage index and how relatively few hospitals generally see wage index declines in excess of 5 percent, hospitals may have difficulty adapting to changes in the wage index of this magnitude all at once. For these reasons, we proposed that, for FY 2021, we would place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index for FY 2020, such that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We stated that this transition would allow the effects of our adoption of the revised CBSA delineations to be phased in over 2 years with no estimated reduction in the wage index of more than 5 percent in FY 2021 (that is, no cap would be applied the second year). As we explained in the proposed rule, we continue to believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in the wage index for FY 2021. We also stated that we believe this transition would afford hospitals adequate time to fully assess any additional reclassification options

available to them (we refer the reader to section III.I.2.c. of the preamble of this final rule for a complete discussion regarding the revised OMB delineations and their effects regarding hospital reclassification). Therefore, for FY 2021, we proposed to again provide for a transition of a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year (FY 2020). We stated that, consistent with the application of the 5 percent cap in FY 2020, the FY 2021 5-percent cap on wage index decreases would be applied to all hospitals that have any decrease in their wage indexes, regardless of the circumstance causing the decline, so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. As we explained in the proposed rule, we believe applying the cap on wage index decreases for all hospitals, regardless of the circumstance causing the decrease, allows CMS to mitigate any significant negative impacts of adopting the new OMB delineations in a manner that is readily identifiable in the wage index tables and promotes greater wage index predictability.

Comment: We received several comments regarding the proposed 5 percent cap transition policy. Some commenters, while opposing the proposed adoption of revised OMB delineations, generally supported the concept of the transition cap for FY 2021 (if the delineations are finalized). Another commenter supported the 5 percent transition cap as a means to reduce overall wage index volatility. Several commenters requested that CMS reduce the amount of potential reduction in FY 2021, and extend transition adjustments to affected hospitals in future years. Other commenters, citing CMS' FY 2015 policy of phasing in transitions when adopting revised OMB delineations, suggested a multiple year transition period. One set of commenters, citing the significant financial losses faced by hospitals and the limited amount of time hospitals have had to prepare, suggested CMS adopt the transition over a multiple year period, with no reduction in 2021, a 2.5 percent cap on losses in FY2022, and a 5 percent cap for FY 2022. Other commenters requested CMS limit individual hospitals' potential losses to 3 percent in FY 2021 and again in FY 2022 to give hospitals a fairer chance to adjust to this unexpected proposal.

Response: We thank all commenters for their suggestions. We note that the last time we adopted significantly revised OMB delineations in FY 2015, CMS finalized an extended transition policy (79 FR 49957–49960) for certain hospitals. We allowed urban hospitals that became rural under the new delineations (and that had no form of wage index reclassification or redesignation) to maintain the wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 years. A similar policy was adopted for rural hospitals located in counties that lost ''Lugar'' status under section 1886(d)(8)(B) of the Act that would no longer be deemed urban and would revert back to rural status. Since rural areas of States typically have lower wage index values, and given the potentially significant payment impacts for these hospitals, we believed additional considerations should be extended to this limited number of hospitals. However, as described in section III.I.3.b of the preamble of this final rule, all the hospitals that would shift from urban to rural in FY 2021 under the revised delineations would also be deemed reclassified as urban under section 1886(d)(8)(B) of the Act to the urban area they currently are assigned. Under the revised OMB delineations, no hospital located in a rural county is losing its ''Lugar'' status under section 1886(d)(8)(B) of the Act and reverting back to rural status. Therefore, the special considerations granted to urban hospitals that became rural in FY 2015 would not be applicable to any hospital in FY 2021.

The other transition adjustment we finalized in FY 2015 was for hospitals that experienced a decrease in wage index values due to the change in labor market area definitions. We implemented a 1-year blended wage index where hospitals received 50 percent of their wage index based on the new OMB delineations that went into effect in FY 2015, and 50 percent of their wage index based on their FY 2014 labor market area. We believe our proposed 5 percent cap transition policy for FY 2021 accomplishes the same policy goal as the transition policy we finalized in FY 2015; limiting potential losses for the upcoming fiscal year, while providing adequate time adjust and evaluate reclassification options. We believe the level of the cap amount, providing that FY 2021 wage index values are at least 95 percent of a hospital's FY 2020 wage index value, would adequately mitigate significant wage index decreases and provide wage index stability for affected hospitals for FY 2021. While we acknowledge that some providers will see negative impacts based upon the adoption of the revised OMB delineations, we also point out that some providers will experience increases in their wage index values due to the adoption of the revised OMB delineations. As we stated previously, CMS has in the past provided temporary adjustments to mitigate significant negative impacts from the adoption of new policies or procedures. However, we do not think it is necessary or appropriate to extend the transition period to additional years, as suggested by some commenters, to allow additional time to adjust to the revised OMB delineations in OMB Bulletin No. 18–04. The revised delineations adopted in FY 2015 were significantly more complex and wide ranging than those we proposed for FY 2021. Although the changes outlined in OMB Bulletin No. 18–04 are more significant than typical OMB delineation revisions issued between decennial censuses, the overall impacts of these revised delineations are still more limited in scope than revisions that accompany the release of decennial censuses. Given this, we do not think it is necessary or appropriate extend the transition period to additional years.

Comment: Another commenter, while supportive of the proposed 5 percent cap for FY 2021, cited that some hospitals obtained rural reclassifications during FY 2020 and requested that that CMS apply the 5 percent cap using the wage index being paid in FY 2020 (which would be based on any such mid-year reclassifications) rather than the one that was included in the FY 2020 IPPS final rule.

Response: We appreciate the commenter's support of the proposed 5 percent cap on wage index decreases for FY 2021. Similar to the policy we applied for the 5 percent cap in FY 2020 (see discussion in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337)), for purposes of applying the 5 percent cap for FY 2021, we are clarifying that the prior year ''final'' wage index value refers to the final amount published in the FY 2020 IPPS/LTCH PPS final rule. We believe that using the publicly available wage indexes from the FY 2020 IPPS final rule facilitates transparency. A hospital can contact its MAC for assistance if it believes the incorrect wage index value was used as the basis for its transition and the MAC can make any appropriate correction.

After consideration of the public comments we received, for the reasons discussed in this final rule and the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposal to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a

hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020.

d. Transition Budget Neutrality

For FY 2021, we proposed to apply a budget neutrality adjustment to the standardized amount so that our transition described in section III.A.2.c. is implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act. In the proposed rule (85 FR 32706), we noted that implementing the transition wage index in a budget neutral manner is consistent with past practice (for example, 79 FR 50372 and 84 FR 42338) where CMS has used its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to budget neutralize transition wage index policies when such policies allow for the application of a transitional wage index only when it benefits the hospital. We stated that we believed, and continue to believe, that it would be appropriate to ensure that such policies do not increase estimated aggregate Medicare payments beyond the payments that would be made had we never proposed these transition policies (79 FR 50372 and 84 FR 42337 through 42338). Therefore, for FY 2021, we proposed to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our transition (described in section III.A.2.c.) is implemented in a budget neutral manner.

Specifically, we proposed to apply a budget neutrality adjustment to ensure that estimated aggregate payments under our transition (described in section III.A.2.c. of the preamble of this final rule) for hospitals that have any decrease in their wage indexes for FY 2021 would equal what estimated aggregate payments would have been without the transition. To determine the associated budget neutrality factor, we compared estimated aggregate IPPS payments with and without the transition.

In the proposed rule, we calculated a budget neutrality adjustment factor (0.998580) based on proposed rule data that we stated would be applied to the FY 2021 standardized amount to achieve budget neutrality for the proposed transition. We noted that this number would be updated, as appropriate, based on final rule data.

We noted in the proposed rule that, consistent with past practice (69 FR 49034 and 79 FR 49963), we were not adopting the revised OMB delineations themselves in a budget neutral manner. We do not believe that the revision to the labor market areas in and of itself constitutes an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

We did not receive any comments regarding our proposal to apply a budget neutrality adjustment to the FY 2021 standardized amount to achieve budget neutrality for the transition described in section III.A.2.c. of the preamble of this final rule. Thus, for the reasons set forth in the final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing this proposal without modification. Please see the table in section II.4.h. of the addendum of this final rule which contains the final transition budget neutrality factor (which is based on final rule data) that will be applied to the FY 2021 standardized amount to achieve budget neutrality for the transition.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html.* We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

For FY 2021, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2021, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS code updates.

B. Worksheet S–3 Wage Data for the FY 2021 Wage Index

The FY 2021 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2017 (the FY 2020 wage indexes were based on data from cost reporting periods beginning during FY 2016).

1. Included Categories of Costs

The FY 2021 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2020, the wage index for FY 2021 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse

anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2021 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

4. Proper Documentation of Physician Time Spent in Part A Administrative Versus Part B Billable Activities

In the last few years, we have received wage index data appeals related to MACs' disallowances of wages and hours that hospitals believe are associated with Part A administrative physician time, but the MACs believe are not properly documented as such, or are in fact, associated with Part B billable activities, which are not included in the wage index. For physicians employed by a hospital, their salaries and hours associated with Part A administrative time, which are included in the wage index, are reported on CMS–2552–10 Worksheet S–3, Part II, line 4, and the salaries and hours of hospital employed physicians associated with billable Part B patient care activities, which are NOT included in the wage index, are reported on Worksheet S–3, Part II, line 5. Specifically, the instructions for lines 4 and 5 state the following:

- *Line 4*—Enter the physician Part A administrative salaries, (excluding teaching physician salaries), that are included in line 1. Also do not include intern and resident (I & R) salary on this line. Report I & R salary on line 7. Subscript this line and report salaries for Part A teaching physicians on line 4.01.
- *Line 5*—Enter the total physician, physician assistant, nurse practitioner and clinical nurse specialist on-call salaries and salaries billed under Part B that are included in line 1. Under Medicare, these services are related to direct patient care and billed separately under Part B. Also include physician salaries for patient care services reported for rural health clinics (RHC) and FQHCs included on Worksheet A, column 1, lines 88 and/or 89 as applicable. Do not include on this line amounts that are included on lines 9 and 10 for the SNF or excluded area salaries. Refer to CMS Pub. 15–1, sections 2313.2.E. and 2182.3.E., for instructions related to keeping time studies to track time spent in Part A versus Part B activities. However, although section 2313.2.E.2. states that, ''A minimally acceptable time study must encompass at least one full week per month of the cost reporting period,'' the contractor makes the final determination on the adequacy of the records maintained. A 2-week semi-annual (every 6 months) time study can be adequate unless the contractor believes that a significant change in the pattern of physician time is likely to occur from one quarter to the next, in which case, the contractor may require more frequent time studies. Adequate documentation must be maintained to support total hours in a manner that is verifiable, and to serve as a condition of payment under Part A.

In addition, for physicians that are not employed by the hospital but are under contract, the wages and hours associated with contract Physician Part A administrative activities are reported on Worksheet S–3, Part II, line 13. No salaries and hours related to Part B activities are allowed. Line 13 states the following:

Line 13—Enter from your records the amount paid under contract (in accordance with the general instructions for contract labor) for Part A physician services—administrative, excluding teaching physician services. DO NOT include contract I & R services (to be included on line 7). DO NOT include the costs for Part A physician services from the home office allocation and/or from related organizations (to be reported on line 15). Do not include wages or hours associated with Part B services. As stated in the General Instructions for Contract Labor, ''the minimum requirement for supporting documentation is the contract itself. If the wage costs, hours, and non-labor costs are not clearly specified in the contract, other supporting documentation is required, such as a representative sample of invoices that specify the wage costs, hours, and non-labor costs.'' Refer to CMS Pub. 15–1, sections 2313.2E and 2182.3.E, for instructions related to keeping time studies to track time spent in Part A versus Part B activities. Adequate documentation must be maintained to support total hours in a manner that is verifiable.

In order to accurately report the wages and hours associated with Part A and Part B activities on lines 4 and 5 and 13 respectively, the providers are required to maintain records as to the allocation of physicians' time between various services to keep track of the amount of time the physicians spend on Part A versus Part B activities. 42 CFR 415.60(b) and CMS Pub. 15–1, chapter 21, section 2182.3.B. Specifically, 42 CFR 415.60(b) states, except as provided in paragraph (d) of the section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, among—

- Physician services to the provider (as described in § 415.55);
- Physician services to patients (as described in § 415.102); and
- Activities of the physician, such as funded research, that are not paid under either Part A or Part B of Medicare.

To facilitate the MAC's review of whether physician wages and hours have been reported correctly, hospitals must submit the physician allocation agreements to the MAC. (See CMS Pub. 15–1, Section 2182.3.E.3. which states that allocation agreements are to be submitted annually as part of the cost report filing process.) In the absence of a written allocation agreement (such as Exhibit 1 in CMS Pub. 15–II, Chapter 40, Section 4004.2 and related instructions for this exhibit on Line 34 of Section 4004.2—that is, instructions for Form CMS–2552–10, Worksheet S–2, Part II, line 34), the MAC assumes that 100 percent of the physician compensation cost is allocated to Part B services (see 42 CFR 415.60(f)(2)). The hospital must maintain the information used to complete the physician allocation agreements as directed in CMS Pub. 15–

1 section 2182.3.E. in order to track time spent in Part A versus Part B activities. This section specifies that the hospital may choose to employ the methodology described in subsection 2313.2.E for a time study but may not be required by the MAC to utilize that specific methodology. Therefore, although section 2313.2.E. states that ''a minimally acceptable time study must encompass at least one full week per month of the cost reporting period,'' the MAC makes the final determination on the adequacy of the records maintained for the allocation of physicians' compensation. A 2-week semi-annual (every 6 months) time study can be adequate unless the MAC believes that a significant change in the pattern of physician time is likely to occur from one quarter to the next, in which case, the MAC may require more frequent time studies (see CMS–2552–10, Worksheet S–3, Part II line 5 instructions). Adequate documentation must be maintained to support total hours in a manner that is verifiable, and to serve as a condition of payment under Part A, that is, total hours worked by the physicians must be based on actual data accumulated during the cost reporting period and may not be imputed (consistent with 42 CFR 413.24 and 415.60(f)(1) and (g)). Non-allowable services that are neither Part A nor Part B services (for example, research, teaching of residents in non-approved programs, teaching and supervision of medical students, writing for medical journals, reasonable availability services in departments/cost centers other than Emergency Room, etc.) are reported as non-reimbursable activities in the designated non-reimbursable cost centers of the Medicare cost report, CMS–2552–10 (for example, Worksheet A, lines 190–194, see 42 CFR 415.60(b)(3)). Reasonable availability services for emergency rooms can be considered Part A in certain circumstances (see PRM–I, section 2109.3.A. through C. for instances when emergency department physician availability services costs are allowable, and for the associated required documentation).

We did not receive any comments on the discussion in this section.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2021 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB Control Number 0938–0050 with expiration date March 31, 2022) for cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017. For wage index purposes, we refer to cost reports during this period as the ''FY 2017 cost report,'' the ''FY 2017 wage data,'' or the ''FY 2017 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the final FY 2021 wage index includes FY 2017 data submitted to us as of the end of June 2020. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2021 wage index, we identified and excluded 84 providers with aberrant data that should not be included in the wage index. However, we stated that if data elements for some of these providers were corrected, we intended to include data from those providers in the final FY 2021 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 19, 2020. For the final FY 2021 wage index, we restored 29 hospitals to the wage index because their data was either verified or improved, but we also removed the data of one hospital for the first time after the proposed rule due to its data being aberrant. Thus, 56 hospitals with aberrant data remain deleted from the final FY 2021 wage index ($84 - 29 + 1 = 56$).

In constructing the proposed FY 2021 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2017, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We stated in the proposed rule (85 FR 32709) that we believe including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed FY 2021 wage index, we removed 8 hospitals that converted to CAH status on or after January 24, 2019, the cut-off date for CAH exclusion from the FY 2020 wage index, and through and including January 24, 2020, the cut-off date for CAH exclusion from the FY 2021 wage index. Since the proposed rule, we learned of 1 more hospital that converted to CAH status on or after January 24, 2019, and through and including January 24, 2020, the cut-off date for CAH exclusion from the FY 2021 wage index, for a total of 9 hospitals that were removed from the FY 2021 wage index due to conversion to CAH status. In summary, we calculated the final FY 2021 wage index using the Worksheet S–3, Parts II and III wage data of 3,222 hospitals.

For the FY 2021 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2021 wage index associated with this final rule (available via the internet on the CMS website), includes separate wage data for the campuses of 16 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
050121	0.82
05B121	0.18
070033	0.93
07B033	0.07
100029	0.54
10B029	0.46
100167	0.38
10B167	0.62
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
330195	0.89
33B195	0.11
330234	0.74
33B234	0.26
340115	0.95
34B115	0.05
360020	0.97
36B020	0.03
390006	0.94
39B006	0.06

CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
390115	0.85
39B115	0.15
390142	0.83
39B142	0.17
460051	0.82
46B051	0.18
510022	0.95
51B022	0.05
670062	0.59
67B062	0.41

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the FY 2021 Unadjusted Wage Index

As we stated in the proposed rule (85 FR 32710), the method used to compute

the FY 2021 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2020 IPPS/LTCH PPS final rule (see 84 FR 42304 through 42307, August 16, 2019), and we did not propose any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2021, these were data from cost reports for cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017). In addition, we included data from some hospitals that had cost reporting periods beginning before October 2016 and reported a cost reporting period covering all of FY 2017. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2017 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2017 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43 − Lines 28, 33 and 35)/ ((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-

related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2016 through April 15, 2018, for private industry hospital workers from the BLS' Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose to make any changes to the usage of the ECI for FY 2021. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306) August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the FY 2021 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306) August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of the Appendix of the final rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the final rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306; August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2016, through April 15, 2018, for private industry hospital workers from the BLS' Compensation and Working Conditions. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose any changes to the usage of the ECI for FY 2021. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2016	11/15/2016	1.02755
11/14/2016	12/15/2016	1.02560
12/14/2016	01/15/2017	1.02370
01/14/2017	02/15/2017	1.02180
02/14/2017	03/15/2017	1.01989
03/14/2017	04/15/2017	1.01803
04/14/2017	05/15/2017	1.01628
05/14/2017	06/15/2017	1.01465
06/14/2017	07/15/2017	1.01306
07/14/2017	08/15/2017	1.01145
08/14/2017	09/15/2017	1.00984
09/14/2017	10/15/2017	1.00822
10/14/2017	11/15/2017	1.00661
11/14/2017	12/15/2017	1.00503
12/14/2017	01/15/2018	1.00341
01/14/2018	02/15/2018	1.00174
02/14/2018	03/15/2018	1.00000
03/14/2018	04/15/2018	0.99814

For example, the midpoint of a cost reporting period beginning January 1, 2017, and ending December 31, 2017, is June 30, 2017. An adjustment factor of 1.01306 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2017, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2021, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the previously described methodology, we stated in the proposed rule (85 FR 32712) that the proposed FY 2021 unadjusted national average hourly wage was the following:

Proposed FY 2021 Unadjusted National Average Hourly Wage	$45.11

We did not receive any comments regarding the discussion of our method for computing the FY 2021 unadjusted wage index. Based on the previously described methodology, the final FY 2021 unadjusted national average hourly wage is the following:

Final FY 2021 Unadjusted National Average Hourly Wage	$45.27

E. Occupational Mix Adjustment to the FY 2021 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered

nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019, FY 2020, and FY 2021 Wage Indexes

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), we collected data in 2016 to compute the occupational mix adjustment for the FY 2019, FY 2020, and FY 2021 wage indexes.

The FY 2021 occupational mix adjustment is based on the calendar year (CY) 2016 survey. Hospitals were required to submit their completed 2016 surveys (Form CMS–10079, OMB number 0938–0907, expiration date September 31, 2022) to their MACs by July 3, 2017. The preliminary, unaudited CY 2016 survey data were posted on the CMS website on July 12, 2017. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2021 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Deadline for Submitting the 2019 Medicare Wage Index Occupational Mix Survey for Use Beginning With the FY 2022 Wage Index

A new measurement of occupational mix is required for FY 2022. The FY 2022 occupational mix adjustment will be based on a new calendar year (CY) 2019 survey. The CY 2019 survey (CMS Form CMS–10079, OMB number 0938–0907, expiration date September 31, 2022) received OMB approval on October 18, 2019. The final CY 2019 Occupational Mix Survey Hospital Reporting Form is available on the CMS website at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/2019-occupational-mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2022*. Hospitals were required to submit their completed 2019 surveys to their MACs (not directly to CMS), on the Excel hospital reporting form, by July 1, 2020 via email attachment or overnight delivery. CMS granted an extension until August 3, 2020 for hospitals nationwide that may be unable to meet the July 1, 2020 deadline amidst the Novel Coronavirus Disease (COVID–19) national emergency. Hospitals should please see the CMS website at the previously mentioned link for information on this extension. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2022 desk review process, the MACs will revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

Comments: We received comments concerning the deadline for submitting the CY 2019 Occupational Mix Survey. Commenters appreciated the extension but requested CMS further extend the deadline for submission of CY 2019 Occupational Mix Surveys to assist hospitals amidst COVID–19. Commenters suggested various deadlines, including September 3rd or after to allow sufficient time for CMS to incorporate the 2019 occupational mix data into the FY 2022 IPPS rates while supporting accurate responses as hospitals dedicate resources to the ongoing public health emergency. Two commenters emphasized that it is vital to ensure accuracy since survey results will be used to adjust the wage index for three years.

One commenter noted that the Occupational Mix Survey has historically been due one month after cost reports are due for hospitals with calendar year (CY) cost reporting year ends, and therefore should be extended consistent with the extension of the cost report due date until August 31 for hospitals with a December 31 Fiscal Year End (FYE). According to this commenter, requiring hospitals to complete the occupational mix survey before their cost reports are due would increase provider burden because hospitals with CY cost reporting periods use the process of completing their Medicare cost reports to complete the occupational mix survey.

Two commenters also asked that if CMS further extends the August 3rd, 2020 deadline, CMS should publicize the extension prior to the publication of the final rule via an update to the Emergency Declaration Blanket Waivers and other vehicles such as list-serve messages or the Tuesday ''Office Hours'' national teleconference.

Response: We value the commenters' input. Due to continued COVID–19 related concerns from hospitals about meeting the August 3 deadline, CMS is further extending this deadline to September 3, 2020. Hospitals must submit their occupational mix surveys along with complete supporting documentation to their MACs by no later than September 3, 2020. The preliminary CY 2019 unaudited occupational mix survey data will be released on the CMS website by September 8, 2020. Hospitals should review their occupational mix survey data in the Public Use File (PUF) on the CMS website to confirm it is correct and may submit revisions to their occupational mix survey data to their MACs, if needed, by no later than September 10, 2020. These revised deadlines are contained in the updated FY 2022 Hospital Wage Index Development Time Table available at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page*.

We believe that this deadline, suggested by one commenter, is the most appropriate because it grants one additional month to the current extension, which will allow hospitals more time to accurately complete the survey while still allowing adequate time for CMS to review the data in time for inclusion in the FY 2022 wage index. Any further delay would jeopardize the FY 2022 wage index timeline and threaten timely implementation of the FY 2022 wage index.

CMS publicized this additional extension prior to the display of the final rule by updating the Emergency Declaration Blanket Waivers at *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf* and the Hospitals: CMS Flexibilities to Fight COVID–19 Fact sheet at *https://www.cms.gov/files/document/covid-hospitals.pdf*, by updating the final CY 2019 Occupational Mix Survey Hospital Reporting Form on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientvppswage-index-files/2019-occupational-mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2022*, by instructing the MACs to contact their hospitals, and by notifying hospitals through a Medicare Learning Network (MLN) Connects list-serve message on July 30, 2020.

In summary, hospitals must submit their occupational mix surveys along with complete supporting documentation to their MACs by no later than September 3, 2020. Hospitals may then submit revisions to their occupational mix survey data as set forth on the CMS website to their MACs, if needed, by no later than September 10, 2020.

3. Calculation of the Occupational Mix Adjustment for FY 2021

For FY 2021, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2021 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this final rule (which is available via the internet on the CMS website), which contains the final FY 2021 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this final rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2021 wage index. For the proposed FY 2021 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,196 hospitals, and we used the occupational mix surveys of 3,113 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,113/3,196). For the proposed FY 2021 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2021 occupational mix adjusted national average hourly wage was the following:

Proposed FY 2021 Occupational Mix Adjusted National Average Hourly Wage	$45.07

We did not receive any comments on our proposed calculation of the occupational mix adjustment to the FY 2021 wage index. Thus, for the reasons discussed in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification, to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index and to apply the occupational mix adjustment to 100 percent of the FY 2021 wage index.

For the final FY 2021 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,223 hospitals, and we are using the occupational mix surveys of 3,140 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,140/3,223). For the final FY 2021 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the final FY 2021 occupational mix adjusted national average hourly wage is the following:

FY 2021 Occupational Mix Adjusted National Average Hourly Wage	$45.23

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2021 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2021, we are applying the occupational mix adjustment to 100 percent of the FY 2021 wage index. We calculated the occupational mix adjustment using data from the 2016 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The FY 2021 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows.

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$41.63
National LPN and Surgical Technician	$24.66
National Nurse Aide, Orderly, and Attendant	$16.96
National Medical Assistant	$18.21
National Nurse Category	$34.97

The national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2016 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42 percent, and the national percentage of hospital employees in the all other occupations category is 58 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 27 percent in one CBSA to a high of 82 percent in another CBSA.

We compared the FY 2021 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. Applying the occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2021 Occupational Mix Adjusted Wage Indexes to the Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	237 (57.5%)
Number of Rural Areas Wage Index Increasing	21 (44.7%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	114 (27.7 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	7 (1.7 %)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	9 (19.1%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0 %)
Number of Urban Areas Wage Index Decreasing	174 (42.2 %)
Number of Rural Areas Wage Index Decreasing	26 (55.3 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	80 (19.4 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	2 (0.5 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8 (17 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0 %)
Largest Positive Impact for an Urban Area	6.39 %
Largest Positive Impact for a Rural Area	3.81 %
Largest Negative Impact for an Urban Area	5.94 %
Largest Negative Impact for a Rural Area	1.66 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0

These results indicate that a larger percentage of urban areas (57.5 percent) would benefit from the occupational mix adjustment than would rural areas (44.7 percent).

G. Application of the Rural Floor, Application of the State Frontier Floor, and Continuation of the Low Wage Index Hospital Policy

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor''. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2021 wage index associated with this final rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 285 hospitals would receive an increase in their FY 2021 wage index due to the application of the rural floor.

Comments: Some commenters noted that several hospitals redesignated as rural under § 412.103 had a wage index in the proposed rule that was lower than the rural floor for their state. The commenters inquired whether this was the result of a calculation error, as CMS has never allowed a hospital within a State to be paid less than the rural floor. If this calculation was intentional, the commenters opposed this policy because (1) the rural reclassification provisions do not create the authority to create a lesser wage index for rural reclassified hospitals as opposed to physically rural hospitals, and (2) CMS did not subject this policy to notice-and-comment rulemaking as required by *Azar* v. *Allina Health Services,* 587 US____, 139 S. Ct. 1804, 1811 (2019).

Response: We thank the commenters for pointing out this inadvertent error and acknowledge that some wage indexes in Table 2 associated with the IPPS/LTCH PPS Proposed Rule were incorrect. We have fixed this error for the final rule so that Table 2 contains the corrected wage index values for FY 2021.

Comment: One commenter recognized the need for a rural floor that is calculated separately from a reclassified rural wage index, but disagreed with the current method of calculating the rural wage index because it could result in a § 412.103 reclassified hospital receiving a rural wage index below that of their original CBSA. To address this issue, the commenter suggested that CMS should calculate each rural reclassified hospital wage index independently by excluding all other reclassified hospitals from the calculation instead of CMS blending the data of all § 412.103 reclassified hospitals with data from geographically rural hospitals.

Response: We agree with the commenter that there is a need for a rural floor that is calculated separately (without the data of hospitals with § 412.103 redesignations) from a reclassified rural wage index, which is calculated including the data of hospitals with § 412.103 redesignations if including that wage data raises the state's rural wage index. In response to the commenter's concern that a hospital may receive a lower wage index as a result of its § 412.103 reclassification if the rural wage index is lower than the wage index of the hospital's geographic CBSA, we note that obtaining a § 412.103 redesignation is a completely voluntary process that hospitals may undertake for a variety of reasons. It behooves a hospital to consider all payment implications, including those on their wage index, prior to reclassifying under § 412.103. We further note that a hospital may mitigate the wage index impact of a § 412.103 rural reclassification by obtaining an MGCRB reclassification, including to its geographic area, which it can decide to keep or withdraw depending on the proposed rule wage indexes for its reclassified or geographic area compared to their state's rural area. Finally, we are aware of many hospitals that obtain § 412.103 redesignations in order to raise their state's rural wage index. In such cases, it is a reasonable assumption that hospitals consider prior to reclassifying under § 412.103 whether potentially lowering their own wage indexes is worthwhile in order to raise the state's rural wage index. For these reasons, we do not believe that it is necessary to change the calculation of the rural reclassified hospital wage index, as the commenter suggests, in an attempt to mitigate possible wage index reductions that hospitals may experience as a result of reclassifying under § 412.103.

2. State Frontier Floor for FY 2021

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32715), we did not propose any changes to the frontier floor policy for FY 2021. In the proposed rule, we stated that 45 hospitals would receive the frontier floor value of 1.0000 for their FY 2021 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2021. In this final rule, 44 hospitals will receive the frontier floor value of 1.0000 for their FY 2021 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000.

The areas affected by the rural and frontier floor policies for the final FY 2021 wage index are identified in Table 2 associated with this final rule, which is available via the internet on the CMS website.

3. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. We also provided for a transition in FY 2020 for hospitals experiencing significant decreases in their wage index values as compared to their final FY 2019 wage index, and made these changes in a budget neutral manner.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, we stated in the proposed rule that this policy will continue in FY 2021. Based on data for the proposed rule, we stated that, for FY 2021, the 25th percentile wage index value across

all hospitals would be 0.8420. In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, we proposed to apply the budget neutrality adjustment in the same manner as we applied it in FY 2020, as a uniform budget neutrality factor applied to the standardized amount.

In addition, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, effective beginning in FY 2020, we remove the data of hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. As previously mentioned in section III.G.1. of this final rule, the rural floor for this FY 2021 final rule is calculated without the wage data of hospitals that have reclassified as rural under § 412.103.

Lastly, for FY 2020, we placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 (84 FR 42336 through 42338). We applied a budget neutrality adjustment to the standardized amount so that this transition policy was implemented in a budget neutral manner. We clarified in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337 through 42338) that this 5-percent cap on wage index decreases applied to all hospitals that have any decrease in their wage indexes, regardless of the circumstance causing the decline, so that a hospital's final wage index for FY 2020 will not be less than 95 percent of its final wage index for FY 2019. In light of the recent OMB updates described in section III.B.2. of this final rule, for FY 2021 we proposed to again cap any decreases in the wage index at 5 percent so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020, and to apply a budget neutrality adjustment for this transition policy in the same manner as in FY 2020. As previously mentioned, on September 14, 2018, OMB issued OMB Bulletin No. 18–04 which established revised delineations. Consistent with our past practice of implementing transition policies to help mitigate negative impacts on hospitals of certain wage index proposals, due to the revised OMB delineations, for FY 2021 we proposed to again provide for a transition of a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year which would be FY 2020. We refer readers to section III.B.2.c. and d. of the preamble of this final rule for a complete discussion of the wage index transition policy.

Comments: We received comments supporting and opposing the continuation of the low wage index hospital policy. Many commenters thanked CMS for implementing this policy in FY 2020 in response to rural and other health care stakeholders' requests that CMS address ''circularity'' in the wage index (the cyclical effect of hospitals with relatively high wages receiving higher reimbursement due to relatively high wage indexes, which allows them to afford paying higher wages) and halt the ''death spiral'' perpetuating wage index disparities where relatively low wage index hospitals are forced to keep wages low due to low Medicare reimbursements that lag behind areas with higher wage indexes.

Other commenters opposed continuing the low wage index hospital policy in FY 2021. The commenters expressed that the policy fails to recognize the legitimate differences in geographic labor markets. Commenters also noted that there is no requirement for hospitals to use the increased reimbursement to boost employee compensation, and suggested CMS begin evaluating the cost report data filed by hospitals in the lowest quartile to ascertain whether the increased funds are being used to raise employee compensation in deciding whether to continue this policy for FY 2022. Some commenters stated that the data lag CMS described in its rationale applies equally to all hospitals, not only those in the lowest quartile. Commenters questioned CMS's statutory authority to promulgate this policy under 42 U.S.C. 1395ww(d)(3)(E), which requires the agency to adjust payments to reflect area difference in wages, because it artificially inflates wage index values and creates a wage index system not based on actual data. These commenters expressed that CMS is using the wage index as a policy vehicle, not as a technical correction, and needs Congressional authority to provide additional funding to low-wage hospitals.

Response: We appreciate the many comments received in support of our policy to provide an increase in the wage index for hospitals with wage index values below the 25th percentile wage index value for a year (referred to as the low wage index hospital policy). We note that we did not propose any changes to this policy in the FY 2021 IPPS/LTCH PPS proposed rule. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), the intent of the low wage index hospital policy is to increase the accuracy of the wage index as a technical adjustment and not to use the wage index as a policy vehicle. As we explained in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327 through 42328), we believe our low wage index hospital policy increases the accuracy of the wage index as a relative measure because it allows low wage index hospitals to increase their employee compensation in ways that we would expect if there were no lag in reflecting compensation adjustments in the wage index.

In response to the commenters opposing our policy because the policy fails to recognize differences in geographic labor markets, we continue to believe, for the reasons stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327–42328), that by preserving the rank order in wage index values, our policy continues to reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Furthermore, as stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327 through 42328), and as noted above, we believe that the low wage index hospital policy increases the accuracy of the wage index as a relative measure of wages across different geographic regions because it allows low wage index hospitals to increase their employee compensation in ways that we would expect if there were no lag in reflecting compensation adjustments in the wage index. Thus, under the low wage index hospital policy, we believe the wage index for low wage index hospitals appropriately reflects the relative hospital wage level in those areas compared to the national average hospital wage level. As explained in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), because the low wage index hospital policy is based on the actual wages that we expect low wage hospitals to pay, it falls within the scope of the authority in section 1886(d)(3)(E) of the Act. We appreciate the commenters' suggestions that CMS evaluate whether hospitals in the lowest

quartile increased employee compensation as a result of our low wage policy. As we stated in the FY 2020 final rule (84 FR 42327), the future wage data from those hospitals will help us assess our reasonable expectation that low wage hospitals would increase employee compensation as a result of our low wage index hospital policy. We intend to assess whether the low wage index hospital policy has been effective in allowing hospitals to make adjustments in employee compensation, as the commenter suggested, based on wage data collected on hospitals' cost reports for the years during which this policy is in effect. In response to the commenters asserting that the data lag applies equally to all hospitals, we agree that the 4 year data lag does not apply only to hospitals in the lowest quartile; however, we believe that circularity inherent in the data lag poses a particular problem for low wage hospitals. As we explained in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328, 42331), we believe many low wage index hospitals have been prevented from increasing compensation because of the lag under our cost reporting process between the time hospitals increase employee compensation and the time these increases are reflected in the wage index.

We refer readers to our discussion in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326–42332) for further discussion of the low wage index hospital policy and our responses to similar comments.

Comment: Many commenters supported increasing the wage index values of low-wage hospitals, but urged CMS to do so in a non-budget-neutral manner. Commenters asserted that this redistribution is counterproductive to CMS's larger goals of high quality care and healthcare access because it forces high-wage, mostly urban hospitals to bear the cost of supporting lower-wage hospitals. Some commenters stated that 42 U.S.C. 1395ww(d)(5)(I) does not authorize budget neutrality adjustments to the national standardized amount, except for transfer cases. Commenters stated that the budget neutrality adjustment penalizes many hospitals, including rural hospitals.

Other commenters asked that CMS ensure that the budget neutrality adjustment factor not apply to hospitals falling below the 25th percentile or revert to its FY 2020 proposal to decrease the wage index for hospitals with values above the 75th percentile. One commenter specifically pointed out that hospitals between the 22nd and the 25th percentile are receiving an overall reduction because the amount of benefit received from the wage index boost is less than the reduction to the standardized rate. This commenter suggested CMS explore slightly reducing the labor share of those hospitals who have a wage index greater than 1.0000, or a graduated reduction to the standardized rate based on wage index percentile.

Response: We disagree with the commenters that the low wage index hospital policy should be implemented in a non-budget neutral manner. As we stated in response to similar comments in the FY 2020 IPPS/LTCH PPS final rule, (84 FR 42331 and 42332), under section 1886(d)(3)(E) of the Act, the wage index adjustment is required to be implemented in a budget neutral manner. However, even if the wage index were not required to be budget neutral under section 1886(d)(3)(E) of the Act, we would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), the wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related costs of subsection (d) hospitals. As a result, as we explained in the FY 2020 IPPS/LTCH PPS final rule, if it were determined that section 1886(d)(3)(E) of the Act does not require the wage index to be budget neutral, we invoke our authority at section 1886(d)(5)(I) of the Act in support of such a budget neutrality adjustment. We have considered the commenters' suggestion that we do not have authority under section 1886(d)(5)(I) of the Act to implement a budget neutrality adjustment to the national standardized amount, including the argument that such authority exists only with respect to transfer cases. Contrary to the commenters' suggestion, and consistent with our response to a similar comment in the FY 2020 IPPS/LTCH PPS final rule, we believe that we have broad authority under section 1886(d)(5)(I) of the Act to promulgate a budget neutrality adjustment to the national standardized amount and that this authority is not limited to transfer cases. We refer readers to the full discussion of budget neutrality for the low wage index hospital policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42328–42332). Regarding the commenters' suggested alternatives, as we explained in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), stakeholders raised reasonable policy arguments that we think we should consider further regarding the relationship between a budget neutrality adjustment targeting high wage index hospitals and the design of the wage index to be a relative measure of the wages and wage-related costs of subsection (d) hospitals in the United States. For similar reasons, we believe the effects of other suggestions made by commenters, including suggestions to apply budget neutrality or to revise the labor related share or standardized amount in a way that targets certain subsets of hospitals, would need to be assessed further. With regard to the commenter's assertion about a possible reduction to overall payment if the amount of benefit received from the wage index boost is less than the reduction to the standardized rate, we believe we have applied both the quartile policy and the budget neutrality policy appropriately. The quartile adjustment is applied to the wage index, which resulted in an increase to the wage index for hospitals below the 25th percentile. The budget neutrality adjustment is applied to the standardized amount in order to ensure that the low wage index hospital policy is implemented in a budget neutral manner. Thus, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act and with how we implemented budget neutrality for the low wage index hospital policy in FY 2020, we think it is appropriate to continue to apply a budget neutrality adjustment to the national standardized amount for all hospitals so that the low wage index hospital policy is implemented in a budget neutral manner for FY 2021.

Comment: Many commenters urged CMS to develop a comprehensive, long-term approach to wage index reform in place of the policy finalized in the FY 2020 rule. Several commenters suggested alternative solutions to address wage index disparities, including: Solutions to help hospitals with wages that are not rising at the pace of the national average; a national wage index floor for all hospitals; an urban wage index floor of 1.0000 for CBSAs located in a metropolitan area with a population of at least 5 million (funded by an adjustment to wage indexes of other similar metropolitan areas with substantially higher wage indexes); wage data audits to verify local labor prices; and limiting ''reclassification stacking'' so that hospitals cannot reclassify as rural and then use the more relaxed requirements afforded to rural hospitals to reclassify to a higher wage index. Other

commenters recommended that CMS proactively address the effects of COVID–19, which the commenters believed would exacerbate wage index disparities, by excluding wage data collected during the public health emergency from future wage index calculations. Another commenter asked that an imputed rural floor be included in any effort to address disparities in the wage index, and that CMS reinstate the imputed floor immediately to more equitably reimburse hospitals in all-urban states considering the extensive time and effort involved in broader wage index reform.

Response: We appreciate the commenters' suggested alternatives. Because we consider these comments to be outside the scope of the FY 2021 IPPS/LTCH PPS proposed rule, we are not addressing them in this final rule but may consider them in future rulemaking.

Comment: Several commenters specifically supported CMS's continuation of the policy from FY 2020 to exclude the wage data of urban hospitals that reclassify to rural when calculating each state's rural floor. Commenters expressed that the change to the calculation of the rural floor limits the ability of hospitals to game the system and supports the overall goal of making the wage index reflective of variances in labor markets. One commenter stated that excluding hospitals reclassified under § 412.103 from the rural floor calculation narrows a loophole used by hospitals in some states to artificially increase the rural floor, which is paid for by hospitals in all states, and urged CMS to find more ways to use regulations to curtail the adverse effects of section 3141 of the Affordable Care Act. This commenter also requested that CMS publish an assessment of the state-specific effects of the rural floor on the IPPS wage index and on all prospective payment systems that are affected by the rural floor.

Response: We appreciate the commenters' support of our policy to exclude the wage data of hospitals reclassified under § 412.103 from the rural floor calculation. As stated in the FY 2020 IPPS/LTCH PPS final rule, we believe this policy is necessary and appropriate to address the unanticipated effects of rural reclassifications on the rural floor and the resulting wage index disparities, including the effects of the manipulation of the rural floor by certain hospitals (84 FR 42333 through 42334). Regarding the commenter's suggestion that CMS find ways to use regulations to curtail the adverse effects of nationwide budget neutrality, we believe this would be difficult to achieve without legislative action, as section 3141 of Public Law 111–148 requires a national budget neutrality adjustment in implementing the rural floor. Finally, in response to the commenter's request that CMS publish an assessment of the state-specific effects of the rural floor on the IPPS wage index and on all prospective payment systems that are affected by the rural floor, we refer the commenter to the impact analysis in Appendix A to this FY 2021 IPPS/LTCH PPS final rule. CMS specifically provides the impacts of the rural floor in section I.G.2 of Appendix A of this final rule, in Table 1 ''Impact Analysis of Final Changes to the IPPS for Operating Costs for FY 2021'' in Column (5) ''Rural Floor with Application of National Rural Floor Budget Neutrality'', including the impact by geographic region separately for rural and urban hospitals. In addition, CMS provides the rural floor wage index value for each state in Table 3 of the proposed and final rules, as well as the national rural floor budget neutrality factor so that hospitals and public are aware of the impact of the rural floor on individual hospitals. CMS also provides public use data files in conjunction with the proposed and final rules that allow for additional analyses by different hospital characteristics, including at the state level. Analysis of the effects of the rural floor for all other payment systems besides IPPS and LTCH that are affected by the rural floor is outside the scope of the IPPS/LTCH PPS final rule. After consideration of the public comments received, for the reasons discussed in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification, to apply a budget neutrality adjustment for our low wage index hospital policy in the same manner as we applied it in FY 2020, as a uniform budget neutrality factor applied to the standardized amount.

As we stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32715), we will continue to apply the policies we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 32715) to address wage index disparities—that is, the low wage index hospital policy, and the exclusion of the wage data of hospitals reclassified under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the rural floor and from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. For purposes of the low wage index hospital policy, based on the data for this final rule, for FY 2021, the 25th percentile wage index value across all hospitals is 0.8465.

H. FY 2021 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the internet on the CMS website. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41380), beginning with FY 2019, we added Table 4 which was titled and included a ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' for the relevant fiscal year. In this FY 2021 IPPS/LTCH PPS final rule, we have included Table 4A which is titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this final rule for a discussion of the wage index tables for FY 2021.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). However, we note that this deadline has been extended for applications for FY 2022 reclassifications to 15 days after the public display date of the FY 2021 IPPS/LTCH final rule at the Office of the Federal Register, using our authority under Section 1135(b)(5) the Act due to the COVID–19 Public Health Emergency. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics

similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). We note that rural hospitals reclassifying under the MGCRB to another state's rural area are not eligible for the rural floor, because the rural floor may apply to urban, not rural, hospitals.

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For a discussion on the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336).

2. MGCRB Reclassification and Redesignation Issues for FY 2021

a. FY 2021 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. At the time this final rule was constructed, the MGCRB had completed its review of FY 2021 reclassification requests. Based on such reviews, there are 392 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2021. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2021, hospitals reclassified beginning in FY 2019 or FY 2020 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 245 hospitals approved for wage index reclassifications in FY 2019 that will continue for FY 2021, and 269 hospitals approved for wage index reclassifications in FY 2020 that will continue for FY 2021. Of all the hospitals approved for reclassification for FY 2019, FY 2020, and FY 2021, based upon the review at the time of this final rule, 895 hospitals are in a MGCRB reclassification status for FY 2021 (with 90 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Comment: Several commenters requested additional time or an additional opportunity for hospitals to revise decisions to withdraw an approved MGCRB reclassification. The commenters explained that if the proposed labor market changes are not finalized, the provider may have inadvertently reduced the wage index that they would receive for FY 2021. One commenter acknowledged that this is a challenge every year as providers may or may not know the actions of other providers, however, the commenter asked for more time for hospitals to make MGCRB elections after the final rule given the challenges that many providers are currently facing financially and the potential for CMS to not finalize the revised labor markets.

Response: We maintain that information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. In addition, section 1886(d)(8)(D) of the Act requires the Secretary to adjust the standardized amounts to ensure that aggregate payments under the IPPS after implementation of the provisions of certain sections of the Act, including section 1886(d)(10) of the Act for

geographic reclassifications by the MGCRB, are equal to the aggregate prospective payments that would have been made absent these provisions. If hospitals were to withdraw or terminate reclassification statuses after the publication of the final rule, as the commenter suggested CMS permit, any resulting changes in the wage index would not have been taken into account when calculating the IPPS standardized amounts in the final rule in accordance with the statutory budget neutrality requirement. Therefore, it is necessary that the values published in the final rule represent the final wage index values reflective of reclassification decisions.

Comment: Commenters pointed out that if CMS does not publish the IPPS final rule until September 1, 2020, the 3-year average hourly wage information that hospitals will need to submit an FY 2022 MGCRB application will be unavailable by the statutory deadline of September 1, 2020 for applications to be submitted for FY 2022 to the MGCRB. The commenters urged CMS to make the final rule data available by August 1 or provide guidance by that date, use its authority under section 1135 of the Act to extend the deadline for hospitals to submit geographic reclassification applications, or allow hospitals to submit incomplete applications to the MGCRB by September 1 that could be supplemented later when the final 3-year average hourly wage data is available.

Response: The commenters are correct that under section 1886(d)(10)(C)(ii) of the Act, geographic reclassification applications for FY 2022 are due to the Medicare Geographic Classification Review Board (MGCRB) by September 1, 2020. Under 42 CFR 412.230(d)(2), the 3-year average hourly wage provided in the FY 2021 IPPS final rule is used for FY 2022 geographic reclassification applications. We understand that hospitals need the 3-year average hourly wage data to complete their MGCRB reclassification applications. Therefore, we made the 3-year average hourly wage file available on August 5, 2020, in advance of the final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files* and notified hospitals that this file is available via a Medicare Learning Network (MLN) Connects list-serve message on August 13, 2020 as well as by contacting national hospital associations.

Additionally, we used our authority under section 1135 of the Act to extend the deadline for hospitals to submit geographic reclassification applications for reclassifications beginning in FY 2022, as the commenters suggested. Due to the COVID–19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) the Act, CMS modified the September 1 deadline to be 15 days after the public display date of the FY 2021 IPPS/LTCH final rule at the Office of the Federal Register. We notified hospitals about this extension via the CMS MGCRB Application website, *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB*, and by updating the Emergency Declaration Blanket Waivers at *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*.

Comment: We received a comment requesting CMS to revise its interpretation of section 1886(d)(8)(C)(ii) of the Act. Section 1886(d)(8)(C)(ii) of the Act requires CMS to evaluate the effects of wage index reclassification on a State's rural wage index, and to not exclude the data of hospitals reclassified under section 1886(d)(8)(B) or (d)(10) of the Act from the calculation of the rural wage index if excluding such data would reduce the rural wage index. The commenter pointed to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43838) in which CMS states that its longstanding policy is to consider reclassified hospitals as a group in deciding whether to include or exclude their data from the rural wage index calculation pursuant to section 1886(d)(8)(C)(ii) of the Act. The commenter claimed that CMS's interpretation of section 1886(d)(8)(C)(ii) of the Act is inconsistent with the plain reading of the statute, and results in the reduction of wage index values for rural hospitals in the State of New Hampshire. The commenter contended that the statute's use of ''or'' in listing the types of reclassification considered under the statute requires CMS to evaluate the effects of MGCRB reclassifications under section 1886(d)(10) of the Act separately and independently from the effects of reclassifications under section 1886(d)(8)(B) of the Act before determining whether any hospital's data should or should not be excluded from the rural wage index. The commenter stated that excluding rural hospitals with MGCRB reclassifications and not excluding ''Lugar'' hospitals (including hospitals deemed urban under section 601(g) of Pub. L. 98–21) from the rural wage index would result in a greater wage index value than would be calculated by excluding all reclassified rural hospitals. Therefore, the commenter contended that the rural wage index should be based on average hourly wage data for three hospitals (two rural hospitals with no form of reclassification, and one deemed urban hospital) while excluding the data for a fourth geographically rural hospital with an active MGCRB reclassification. The commenter also questioned CMS' wage index calculation methodologies in response to an email exchange with CMS earlier in the year.

Response: We do not agree that our interpretation of section 1886(d)(8)(C)(ii) of the Act is inconsistent with the plain reading of the statute. As we stated in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43838), given the statutory language referring to ''hospitals'' in the plural under section 1886(d)(8)(C)(i) and 1886(d)(8)(C)(ii) of the Act, our longstanding policy is to consider reclassified hospitals as a group in deciding whether to include or exclude their data from both the urban and rural wage index calculations. For the FY 2021 New Hampshire rural wage index calculation, we excluded the wage index for the two reclassified hospitals located in rural counties, since doing so would not reduce the rural wage index. We believe that CMS's longstanding policy in applying this statute is both a permissible and reasonable interpretation of the statute. Both reclassification under sections 1886(d)(10) and 1886(d)(8)(B) of the Act serve the same essential wage index functions, that is, assigning a hospital a wage index value for a nearby labor market area, and thus we think our current application of section 1886(d)(8)(C)(ii) of the Act is reasonable. We do not believe section 1886(d)(8)(C)(ii) of the Act requires that such reclassifications be considered separately and independently for purposes of applying the rural wage index ''hold harmless'' policy in that section. Therefore, we are not altering our current application of that statute. Finally, in regards to the commenter's questions in response to an email exchange with CMS earlier in the year, CMS previously clarified an error included in that initial email exchange, which we believe resolved the commenter's question regarding the rural wage index calculation methodology.

b. Hospitals With One or Two Years of Wage Data Seeking MGCRB Reclassification

We proposed to modify the regulation at § 412.230(d)(2)(ii)(A) to clarify that a hospital may qualify for an individual wage index reclassification by the MGCRB under § 412.230 to another

labor market area if the hospital only has 1 or 2 years of wage data. Section 412.230(d)(2)(ii)(A) provides that, for hospital-specific wage data, a hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index. In the proposed rule (85 FR 32717), we noted that in certain circumstances, such as that of a new hospital, a hospital may not have 3 years of published wage data within the applicable 3-year average hourly wage period used by the MGCRB. In such cases, it has been CMS's longstanding policy that a hospital must accumulate at least 1 year of wage data within the applicable 3-year average hourly wage period used by the MGCRB, in order to apply for individual reclassification. In the proposed rule, we stated that we were concerned that this policy may not be clear in the current regulation text at § 412.230(d)(2)(ii)(A), and we proposed to revise § 412.230(d)(2)(ii)(A) to clarify this. For hospitals that have accumulated fewer than 3 years of wage data within the applicable 3-year average hourly wage period used by the MGCRB, the appropriate hospital-specific wage data to be used by an applicant under § 412.230(d) is either the single year of published wage data (if the hospital has accumulated just 1 year of wage data), or, if applicable, the weighted average of its 2 years of wage data within the 3-year period reviewed by the MGCRB. Although § 412.230(d)(2)(iv) reflects this longstanding policy as it pertains to new providers, we noted that this policy has not been limited to new providers. Section 412.230(d)(2)(iv) specifies that if a new owner does not accept assignment of the hospital's provider agreement, the hospital is considered a new provider with a new provider number, and the wage data associated with the previous hospital's provider number cannot be used to calculate the new hospital's 3-year average hourly wage. Section 412.230(d)(2)(iv) further states that, in this case, the new hospital would be eligible to apply for an individual MGCRB reclassification after accumulating at least 1 year of wage data (we refer readers to the FY 2003 IPPS/LTCH final rule (67 FR 50066) for further discussion of this policy). As previously noted, however, we have not limited this wage data policy to new providers, and thus we proposed to revise § 412.230(d)(2)(ii)(A) to clarify this. Specifically, we proposed to reformat § 412.230(d)(2)(ii)(A) so that it consists of two paragraphs (paragraphs (d)(2)(ii)(A)(*1*) and (*2*)), and to include new language in new § 412.230(d)(2)(ii)(A)(*2*) stating that once a hospital has accumulated at least 1 year of wage data in the applicable 3-year average hourly wage period used by the MGCRB, the hospital is eligible to apply for reclassification based on those data. We further stated in the proposed rule that, consistent with our current policy, hospitals without wage data or that have accumulated less than 1 year of wage data would not be eligible for individual wage index reclassification.

Comment: We received multiple comments in support of this proposal.

Response: We appreciate commenters' support of our proposed revisions to § 412.230(d)(2)(ii)(A).

After consideration of comments received, for the reasons discussed in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing our proposed revisions to § 412.230(d)(2)(ii)(A) without modification. Specifically, we are reformatting § 412.230(d)(2)(ii)(A) so that it consists of two paragraphs (paragraphs (d)(2)(ii)(A)(1) and (2)), and including new language in new § 412.230(d)(2)(ii)(A)(2) stating that once a hospital has accumulated at least 1 year of wage data in the applicable 3-year average hourly wage period used by the MGCRB, the hospital is eligible to apply for reclassification based on those data.

c. Effects of Implementation of Revised OMB Labor Market Area Delineations on Reclassified Hospitals

(1) Assignment Policy for Hospitals Reclassified to CBSAs Where One or More Counties Move to a New or Different Urban CBSA

We stated in the proposed rule (85 FR 32717) that because hospitals that have been reclassified beginning in FY 2019, 2020, or 2021 were reclassified based on the current labor market delineations, if we adopt the revised OMB delineations based on the OMB Bulletin No. 18–04 beginning in FY 2021, the areas to which they have been reclassified, or the areas where they are located, may change. We stated that under the revised OMB delineations, some existing CBSAs would be reconfigured. Hospitals with current reclassifications were encouraged to verify area wage indexes on Table 2 in the appendix of proposed rule, and confirm that the areas to which they have been reclassified for FY 2021 would continue to provide a higher wage index than their geographic area wage index. We stated that hospitals could withdraw or terminate their FY 2021 reclassifications by contacting the MGCRB within 45 days from the date the proposed rule was issued in the **Federal Register** (§ 412.273(c)).

As we stated in the proposed rule, in some cases, adopting the revised OMB delineations would result in counties splitting apart from CBSAs to form new CBSAs, or counties shifting from one CBSA designation to another CBSA. We noted that reclassifications granted under section 1886(d)(10) of the Act are effective for 3 fiscal years so that a hospital or county group of hospitals would be assigned a wage index based upon the wage data of hospitals in a nearby labor market area for a 3-year period. We explained that if CBSAs are split apart, or if counties shift from one CBSA to another under the revised OMB delineations, we must determine which reclassified area to assign to the hospital for the remainder of a hospital's 3-year reclassification period if the area to which the hospital reclassified split or had counties shift to another new or modified urban CBSA.

Consistent with the policy CMS implemented in the FY 2005 IPPS final rule (69 FR 49054 through 49056) and in the FY 2015 IPPS final rule (79 FR 49973 through 49977), for FY 2021, we stated in the proposed rule (85 FR 32717) that if a CBSA would be reconfigured due to adoption of the revised OMB delineations and it would not be possible for the reclassification to continue seamlessly to the reconfigured CBSA, we believe it would be appropriate for us to determine the best alternative location to reassign current reclassifications for the remaining 3 years. Therefore, to maintain the integrity of a hospital's 3-year reclassification period, we proposed that current geographic reclassifications (applications approved effective for FY 2019, FY 2020, or FY 2021) that would be affected by CBSAs that are split apart or counties that shift to another CBSA under the revised OMB delineations, would ultimately be assigned to a CBSA under the revised OMB delineations that contains at least one county from the reclassified CBSA under the current FY 2020 definitions, and would be generally consistent with rules that govern geographic reclassification. That is, consistent with the policy finalized in FY 2015 (79 FR 49973), we proposed a policy that affected reclassified hospitals be assigned to a CBSA that would contain the most proximate county that—(1) is located outside of the hospital's FY 2021 geographic labor market area, and (2) is part of the original CBSA (as of FY 2020) to which the hospital is reclassified. (We also noted that we made a minor

modification to this proposed assignment policy for certain hospitals currently reclassified to their current geographic CBSA (that is, we stated that we would not require these reclassifications to be assigned to a CBSA outside the hospital's FY 2021 geographic labor market area)). As we explained in the proposed rule, we believe that assigning reclassifications to the CBSA that contains the nearest county that meets the aforementioned criteria satisfies the statutory requirement at section 1886(d)(10)(v) of the Act by maintaining reclassification status for a period of 3 fiscal years, while generally respecting the longstanding principle of geographic proximity in the labor market reclassification process. For county group reclassifications, we stated that we would follow our proposed policy, as previously discussed, except that, for county group reclassifications, we proposed to reassign hospitals in a county group reclassification to the CBSA under the revised OMB delineations that contains the county to which the majority of hospitals in the group reclassification are geographically closest. We also proposed to allow such hospitals, or county groups of hospitals, to submit a request to the *wageindex@cms.hhs.gov* mailbox for reassignment to another CBSA that would contain a county that is part of the current FY 2020 CBSA to which it is reclassified if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules, as described later in this section.

In the proposed rule (85 FR 32718), we recognized that the proposed reclassification reassignment policy, as previously described, for hospitals that are reclassified to CBSAs that would split apart or to counties that would shift to another CBSA under the revised OMB delineations may result in the reassignment of the hospital for the remainder of its 3-year reclassification period to a CBSA having a lower wage index than the wage index that would have been assigned for the reclassified hospital in the absence of the adoption of the revised OMB delineations. Therefore, as discussed in section III.B.2.e. of the preamble of the proposed rule, as a transition, we proposed to continue to apply for FY 2021 a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index for the prior fiscal year. In other words, we stated we would apply a 5 percent cap in FY 2021 on any decrease in a hospital's wage index compared to its final wage index for FY 2020. We explained that we believe that this transitional wage index would mitigate significant negative payment impacts for FY 2021, and would afford hospitals adequate time to fully assess any additional reclassification options available to them.

We noted that if the CBSA to which a hospital is reclassified experiences only a change in name and/or number, (in other words, a county (or county equivalent) did not move to a new or different CBSA), we considered the CBSA, and associated reclassifications, to remain unchanged. For example, we noted that any hospital reclassified to current CBSA 19380 (Dayton, OH), 39140 (Prescott, AZ) or 43524 (Silver Spring-Frederick-Rockville, MD) would have its reclassification transferred to the equivalent CBSA 19430 (Dayton-Kettering, OH), 39150 (Prescott Valley-Prescott, AZ), and 23224 (Frederick-Gaithersburg-Rockville, MD), respectively.

In the proposed rule (85 FR 32718), we provided the following Table 1 which sets forth a list of current FY 2020 CBSAs (column 1) where one or more counties would be relocated to a new or different urban CBSA. We stated that hospitals with MGCRB reclassifications into the CBSAs in column 1 would be subject to the proposed reclassification assignment policy. The third column of ''eligible'' CBSAs lists all revised CBSAs that contain at least one county that is part of the current FY 2020 CBSA (in column 1).

Current CBSA	Current CBSA Name	Eligible Assignment CBSAs
16974	Chicago-Naperville-Arlington Heights, IL	16984, 20994
20524	Dutchess County-Putnam County, NY	39100, 35614
26580	Huntington-Ashland, WV-KY-OH	26580, 16620
28940	Knoxville, TN	28940, 34100
35084	Newark, NJ-PA	35084, 35154
35614	New York-Jersey City-White Plains, NY-NJ	35614, 35154, 39100
38660	Ponce, PR	38660, 49500

In the proposed rule, we provided the following Table 2 which lists all hospitals subject to our proposed reclassification assignment policy and where their reclassifications would be assigned for FY 2021 under this policy. We stated in the proposed rule that the table lists reclassifications that would be in effect for FY 2021 under our proposed policy, and included in Table 2 in the addendum of the proposed rule. We stated that the table also includes reclassifications (noted by an asterisk on the ''MGCRB Case Number'') that were approved in FY 2019 or FY 2020 and are superseded by a new FY 2021 reclassification. We explained that these prior year reclassifications, frequently referred to as ''fallback'' reclassifications, may become active if the subsequent FY 2021 reclassification is withdrawn. (We noted that the table did not include hospitals currently reclassified to their ''home'' geographic area, which were discussed in a separate section of the proposed rule).

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Table 2. Hospitals Subject to Proposed Reclassification Assignment Policy

CCN	MGCRB Case	Current Approved CBSA	Assigned CBSA
07B033	20C0067*	35614	35614
140029	19G0188	16974	16984
140030	19G0188	16974	16984
140155	20G0271	16974	16984
140161	19C0122	16974	16984
140174	19G0188	16974	16984
140186	20G0271	16974	16984
140211	19G0188	16974	16984
140217	19G0188	16974	16984
140286	19G0189	16974	16984
150002	19G0186	16974	16984
150004	19G0186	16974	16984
150008	19G0186	16974	16984
150015	19C0182	16974	16984
150034	19G0186	16974	16984
150035	20C0214	16974	16984
150090	19G0186	16974	16984
150125	19G0186	16974	16984
150126	19G0186	16974	16984
150165	19G0186	16974	16984
150166	19G0186	16974	16984
180005	21C0002	26580	26580
180044	20C0328	26580	26580
180069	20C0076	26580	26580
180078	20C0164	26580	26580
310002	21G0336	35614	35614
310009	21G0336	35614	35614
310015	20G0138	35614	35614
310017	20G0138	35614	35614
310021	19G0047	35084	35084
310044	19G0047*	35084	35084
310044	21C0078	35614	35154
310050	20G0138	35614	35614
310051	19C0135	35614	35154
310054	21G0336	35614	35614
310060	21G0035	35084	35084
310064	21C0026	35614	35154
310076	21G0336	35614	35614
310083	21G0336	35614	35614
310092	19G0047	35084	35084
310096	21G0336	35614	35614

CCN	MGCRB Case	Current Approved CBSA	Assigned CBSA
310110	19G0047	35084	35084
310115	21G0035	35084	35084
310119	21G0336	35614	35614
330023	20G0265	35614	35614
330049	20G0265	35614	35614
330224	20C0127	20524	39100
33B234	20G0265	35614	35614
330386	19C0063	35614	39100
360008	20C0195	26580	26580
390027	21C0393	35614	35154
390049	19C0027	35084	35084
390133	19C0118	35084	35084
390162	21C0350	35084	35084
390201	21C0050	35084	35084
390258	21C0371	35084	35084
390270	19C0220	35084	35084
440056	20G0233	28940	28940
510022	19C0040	26580	26580
520059	21C0233	16974	16984
520096	19C0152*	16974	16984
520102	21C0234	16974	16984

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We stated in the proposed rule (85 FR 32720) that if a hospital that is subject to the proposed reclassification assignment policy discussed earlier in this section wished to be reassigned to another eligible CBSA (that is, to a CBSA other than the CBSA to which their reclassification would be assigned under the proposed reclassification assignment policy and that contains at least one county from the CBSA to which they are reclassified for FY 2020) for which they meet the applicable proximity criteria, they could request reassignment within 45 days from the date the proposed rule is placed on display at the **Federal Register**. We stated that hospitals must send a request to *WageIndex@cms.hhs.gov* and provide documentation establishing that they meet the requisite proximity criteria for reassignment to an another eligible CBSA that contains one or more counties from the CBSA to which they are currently reclassified for FY 2020. For purposes of clarification, we note that the phrase ''CBSA to which they are currently reclassified for FY 2020'' refers to the CBSA to which the hospital currently has an approved reclassification as that CBSA was configured in FY 2020. We explained that we believe this option of allowing these hospitals to submit a request to CMS would provide hospitals with greater flexibility with respect to their reclassification reassignment, while ensuring that the proximity requirements are met. We further explained that we believe that where the proximity requirements are met, the reclassified wage index would be consistent with the labor market area to which the hospitals were originally approved for reclassification. Thus, we stated that a hospital that is subject to our proposed reclassification assignment policy may request to reassign an individual reclassification to any CBSA that contains a county from the CBSA to which it is currently reclassified. However, we noted that to be reassigned to an area that is not the most proximate to the hospital, we believe it is necessary that the hospital demonstrates that it complies with the applicable proximity criteria. We stated that if a hospital cannot demonstrate proximity to a different eligible CBSA, the hospital would not be considered for reclassification to that labor market area, and the reclassification would remain with the CBSA assigned under the proposed reclassification assignment policy described earlier in this section. We stated that in the case of a county group reclassification, all requests for reassignment must include all active hospitals (that is, excluding any hospital that has since closed or converted to a different provider type) included on the original MGCRB reclassification application. We further explained that county groups must also demonstrate that they meet the appropriate proximity requirements, including, for rural county groups, being adjacent to the MSA to which they seek redesignation (§ 412.232(a)(1)(ii)), and for urban county groups, being in the same Combined Statistical Area or Core-Based Statistical Area as the urban area to which they seek redesignation (§ 412.234(a)(3)(iv)).

We stated that all hospital requests for reassignment should contain the hospital's name, address, CCN, and point of contact information, and all requests must be sent to *WageIndex@cms.hhs.gov*. We stated that changes to a hospital's CBSA assignment on the basis of a hospital's disagreement with our determination of closest county, or on the basis of being granted a reassignment due to meeting applicable proximity criteria to an alternate eligible CBSA would be announced in the FY 2021 IPPS/LTCH PPS final rule.

We received three timely requests for reassignment to the *WageIndex@cms.hhs.gov* mailbox. CCN 310051 requested reassignment of MGCRB case 19C0135 from CBSA 35154 to 35614. CCN 390162 requested reassignment of MGCRB case 21C0350 from CBSA 35084 to 35154. Both these requests included adequate documentation to determine that the hospitals met the applicable proximity requirements for reassignment to an eligible CBSA. These requests are approved, and are listed in final Table 2 provided later in this

section and reflected in Table 2 of the addendum to the this final rule. We note these reassignments will be in effect for FY 2021 and any remaining years the reclassification. A third request was received from CCN 390027 (MGCRB case number 21C0393) to be reassigned to either CBSA 35614 or to CBSA 12100. The request did not provide adequate documentation to determine that the hospital met applicable proximity requirements to CBSA 35614, and as described in final Table 1 provided later in this section, CBSA 12100 is not an eligible CBSA for a reclassification approved to CBSA 35614. Therefore, this request is denied.

Comment: Multiple commenters noted that hospitals that were approved for reclassification to the current CBSA 35614 (New York City-Jersey City-White Plains, NY-NJ) were assigned to a different CBSA under CMS's proposed reclassification assignment policy. These commenters contended that if the revised delineations are finalized, the approved reclassifications to CBSA 35614 would be inappropriately modified by CMS. The commenters further contended that hospitals that have been approved for reclassification to that CBSA must be reclassified to that specific CBSA. The commenters stated that section 1886(d)(10)(D)(v) of the Act, requires that a reclassification ''shall be effective for a period of 3 fiscal years.'' A commenter stated that through this provision, Congress specifically removed CMS' discretion to terminate or modify the approved reclassification. Another commenter stated that by assigning an approved reclassification from CBSA 35614 to the CBSA 35154 (New Brunswick-Lakewood, NJ), CMS is violating its own regulations since § 412.230(a)(5)(i) prohibits hospitals from reclassifying to a CBSA with a lower 3-year hourly wage. Citing the severe financial implications for these hospitals, commenters requested CMS to reinstate the reclassifications to CBSA 35614 or provide hospitals with the opportunity to reapply to a different CBSA, effective for FY 2021.

Response: As we discussed in the proposed rule, under the revised OMB delineations, some existing CBSAs would be reconfigured by counties splitting apart from CBSAs to form new CBSAs, or counties shifting from one CBSA designation to another CBSA. As we further explained in the proposed rule, if a hospital is reclassified to a CBSA that would be reconfigured in this manner under the revised delineations, such that the CBSA, as configured in FY 2020, no longer exists, we must determine which reclassified area to assign to the hospital for the remainder of the hospital's 3 year reclassification period. We believe that our proposal to assign affected reclassified hospitals to the CBSA that would contain the most proximate county that (1) is located outside the hospital's proposed FY 2021 geographic labor market area, and (2) is part of the CBSA to which the hospital currently has an approved reclassification (as configured in FY 2020) satisfies the requirement of section 1886(d)(10)(D)(v) of the Act by allowing the hospital to retain reclassification status for a period of three fiscal years, while generally respecting the longstanding principle of geographic proximity in the geographic reclassification process. The New York-Jersey City-White Plains, NY-NJ metropolitan division of the New York-Newark-Jersey City, NY-NJ MSA is listed as CBSA 35614 in both the current and the revised labor market delineations. However, CMS has determined that the configuration of the CBSA would be fundamentally altered between FY 2020 and FY 2021 under the revised OMB delineations. As discussed in section III.A.2.b of this final rule, under the revised OMB delineations, three counties in New Jersey (Ocean, Monmouth, and Middlesex Counties) and one county in NY (Orange County, NY) were split off from CBSA 35614 into a different urban CBSA. While the modifications to CBSA 35614 did not result in a name or number change, as discussed previously in this section, CBSA names and identification numbers are not the basis for determining whether the proposed reclassification assignment policy applies. Because the configuration of CBSA 35614 would be altered under the revised OMB delineations, we believe current reclassifications to this CBSA are appropriately subject to our proposed reclassification assignment policy as discussed above. We agree with commenters that CMS is obligated by the statute to maintain reclassification status for a period of 3 years after approval. However, since the CBSA to which the hospitals were approved has been reconfigured, we believe the FY 2020 CBSA 35614 is not the same entity as the revised FY 2021 CBSA. Consistent with the policy CMS implemented in the FY 2005 IPPS final rule (69 FR 49054 through 49056) and in the FY 2015 IPPS final rule (79 FR 49973 through 49977), for FY 2021, we believe our proposed reclassification assignment policy appropriately satisfies the requirement of section 1886(d)(10)(D)(v) of the Act by allowing the hospital to retain reclassification status for a period of three fiscal years, while generally respecting the longstanding principle of geographic proximity in the geographic reclassification process. This proposed reclassification assignment policy allows the hospital to continue its three year reclassification where, under the revised OMB delineations, the reclassified CBSA originally approved by the MGCRB no longer exists. Of the hospitals with a current approved reclassification to CBSA 35614 that were assigned to a CBSA other than CBSA 35614 (excluding CCN 310051 that was reassigned to CBSA 35614, as discussed previously), none meet the applicable proximity criteria under the revised OMB delineations to be approved to CBSA 35614. For example, one hospital that was originally approved for reclassification to CBSA 35614 by being located 14.8 miles from the border of CBSA 35614, is now located over 80 miles from the revised CBSA. If such a reclassification was assigned to CBSA 35614, we believe this outcome would be inconsistent with the proximity rules that govern reclassifications.

Regarding the comment that our policy violates the regulations at § 412.230(a)(5)(i) that prohibit hospitals from reclassifying to a CBSA with a lower pre-reclassified average hourly wage, we do not agree that this regulation would be violated through application of our proposed reclassification assignment policy. The regulations at § 412.230 apply at the time individual hospitals initially seek reclassification to another area via application to the MGCRB. The reclassification assignment policy, as described in this section, is not an initial reclassification based on an application. Rather, we are assigning already existing approved reclassifications to other appropriate areas in a consistent manner in response to adopting revised OMB delineations. We acknowledge that the new OMB delineations may, in some cases, result in a hospital being assigned a wage index in its reclassified CBSA that is lower than its geographic area wage index. However, this result (a hospital receiving a wage index in its reclassified area that is lower than the wage index in its home area) is not a unique situation and often occurs due to the effects of hold harmless policies at section 1886(d)(8)(C) of the Act. We believe that the most appropriate remedy in these situations would be for hospitals to evaluate their reclassification wage index and, if necessary, withdraw or terminate their reclassifications per regulations at

§ 412.273. In fact, in the proposed rule, we encouraged hospitals with current reclassifications to verify area wage indexes as set forth in Table 2 of the proposed rule and confirm that the areas to which they have been reclassified for FY 2021 would continue to provide a higher wage index than their geographic area wage index. We stated that hospitals could withdraw or terminate their FY 2021 reclassifications, if necessary, in accordance with § 412.273(c). We note, one commenter did withdraw their reclassification to CBSA 35614.

Finally, in response to comments requesting CMS allow affected hospitals to submit expedited applications effective for FY 2021 to obtain a different wage index reclassification, we believe this action is unnecessary and would not be permitted under the statute. Under section 1886(d)(10)(C)(ii) of the Act, a hospital must submit a reclassification application to the MGCRB not later than 13 months before the fiscal year in which the reclassification is to take effect. Thus, applications for reclassifications effective in FY 2021 were due to the MGCRB on September 1, 2019. We note that in the proposed rule, hospitals were offered an opportunity to request assignment to an another eligible CBSA (other than the one to which they were assigned under our proposed reassignment policy) for which they met the applicable proximity criteria within 45 days from the date the proposed rule was placed on display at the **Federal Register**. In addition, as stated in section III.A.2.c of this final rule, we have finalized a transition policy that will help mitigate significant negative payment impacts for FY 2021 and provide hospitals additional time to evaluate other potential reclassification options.

After consideration of the public comments received, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing the reclassification assignment policy as proposed, without modification.

The following final Table 1 sets forth a list of current FY 2020 CBSAs (column 1) where one or more counties will be relocated to a new or different urban CBSA beginning in FY 2021. Hospitals that are currently approved for MGCRB reclassification into the CBSAs in column 1 are subject to our final reclassification assignment policy. The third column of ''eligible'' CBSAs lists all revised CBSAs that contain at least one county that is part of the current FY 2020 CBSA (in column 1). Reclassifications to one of the seven CBSAs identified in Table 1 will be assigned, effective October 1, 2020, to the revised CBSA listed in Table 2. We note that these assignments will remain in effect for the remaining years of the reclassification.

Current CBSA	Current CBSA Name	Eligible Assignment CBSAs
16974	Chicago-Naperville-Arlington Heights, IL	16984, 20994
20524	Dutchess County-Putnam County, NY	39100, 35614
26580	Huntington-Ashland, WV-KY-OH	26580, 16620
28940	Knoxville, TN	28940, 34100
35084	Newark, NJ-PA	35084, 35154
35614	New York-Jersey City-White Plains, NY-NJ	35614, 35154, 39100
38660	Ponce, PR	38660, 49500

The following Table 2 lists all hospitals subject to our final reclassification assignment policy and where their reclassifications will be assigned beginning FY 2021 under this policy. This table lists reclassifications that will be in effect beginning FY 2021 under our final policy, and are included in Table 2 in the addendum of this final rule. This table also lists reclassifications (marked with an asterisk), that have been withdrawn or terminated for FY 2021, but could be reinstated for future years. Reclassifications in the proposed Table 2 set forth earlier that were withdrawn or terminated effective for FY 2021 and cannot be reinstated in FY 2022 have been removed from this final table. We note that two hospitals (marked with **) were approved for reassignment to a different eligible CBSA than the CBSA they would be assigned to under our reclassification assignment policy, as discussed earlier in this section.

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Table 2. Hospitals Subject to Reclassification Assignment Policy

CCN	MGCRB Case	Current Approved CBSA	Assigned CBSA
07B033	20C0067	35614	35614
140155	20G0271	16974	16984
140161	19C0122	16974	16984
140186	20G0271	16974	16984
150002	19G0186	16974	16984
150004	19G0186	16974	16984
150008	19G0186	16974	16984
150015	19C0182	16974	16984
150034	19G0186	16974	16984
150035	20C0214	16974	16984
150090	19G0186	16974	16984
150125	19G0186	16974	16984
150126	19G0186	16974	16984
150165	19G0186	16974	16984
150166	19G0186	16974	16984
180005	21C0002	26580	26580
180044	20C0328	26580	26580
180069	20C0076	26580	26580
180078	20C0164	26580	26580
310002	21G0336	35614	35614
310009	21G0336	35614	35614
310015	20G0138	35614	35614
310017	20G0138	35614	35614
310021	19G0047	35084	35084
310044	21C0078	35614	35154
310050	20G0138	35614	35614
310051	19C0135	35614	35614**
310054	21G0336	35614	35614
310060	21G0035*	35084	35084
310064	21C0026*	35614	35154

CCN	MGCRB Case	Current Approved CBSA	Assigned CBSA
310076	21G0336	35614	35614
310083	21G0336	35614	35614
310096	21G0336	35614	35614
310110	19G0047	35084	35084
310115	21G0035*	35084	35084
310119	21G0336	35614	35614
330023	20G0265	35614	35614
330049	20G0265	35614	35614
330224	20C0127	20524	39100
33B234	20G0265	35614	35614
330386	19C0063	35614	39100
360008	20C0195	26580	26580
390027	21C0393	35614	35154
390049	19C0027	35084	35084
390133	19C0118	35084	35084
390162	21C0350	35084	35154**
390201	21C0050	35084	35084
390270	19C0220	35084	35084
440056	20G0233	28940	28940
510022	19C0040	26580	26580
520059	21C0233	16974	16984
520096	19C0152	16974	16984
520102	21C0234	16974	16984

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(2) Treatment for Hospitals Reclassified to Their Geographic CBSA

Under the previous assignment policy implemented in FY 2015 IPPS/LTCH PPS final rule, a hospital reclassified to a CBSA that had one or more counties moved to a new of different urban CBSA was required to be assigned a new or revised CBSA that is *different* than its geographic CBSA (79 FR 49974 and 49975). We adopted the policy that the assigned CBSA must be *different* than the hospital's geographic area to ensure that a hospital that qualified for reclassification to a different area continued to be eligible to receive a different wage index than its home area. We stated in the proposed rule (85 FR 32720) that we continue to believe this is the appropriate policy for hospitals that originally reclassified to a different area. However, as noted in the prior section, for hospitals currently reclassified to their current geographic CBSA, we proposed to implement a reclassification assignment policy consistent with the policy implemented in FY 2015, with a minor modification in that we would not require these reclassifications to be assigned to a CBSA outside the hospital's FY 2021 geographic labor market area. In the proposed rule (85 FR 32721), we explained that since the FY 2015 IPPS/LTCH final rule was issued, CMS has allowed, under certain circumstances, a hospital to seek an MGCRB wage index reclassification to its own geographic CBSA. We referred readers to a comment response in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56925) discussing such a scenario. We further explained that in these cases, the hospitals are assigned the same wage index value as other hospitals located in its geographic labor market area, not the wage index assigned to hospitals reclassified to that area. We proposed to assign ''home area'' reclassifications to the hospital's proposed geographic CBSA. We noted that the assigned ''home area'' reclassification CBSA may be different from previous years if the hospital is located in a county that was relocated to a new or different urban CBSA. In the proposed rule, we provided the following table listing hospitals with current ''home area'' reclassifications to one of the seven CBSAs (identified in Table 1 of the proposed rule) where one or more counties would move to a new or different urban CBSA, and each hospital's assigned CBSA (column 4).

Table 3. Home Area Reclassifications Subject to Assignment Policy

CCN	MGCRB Case	Current Approved CBSA	Assigned CBSA
140008	21C0243	16974	16984
140054	21C0246	16974	16984
140065	21C0304	16974	16984
140080	21C0305	16974	16984
140082	21C0373	16974	16984
140088	21C0187	16974	16984
140117	21C0306	16974	16984
140119	21C0126	16974	16984
140150	21C0116	16974	16984
140172	21C0096	16974	16984
140179	21C0287	16974	16984
140180	21C0308	16974	16984
140223	21C0236	16974	16984
140258	21C0309	16974	16984
140276	21C0245	16974	16984
140281	21C0075	16974	16984
140290	21C0310	16974	16984
330273	19G0250	35614	35614
440015	19C0206	28940	28940
440125	19C0276	28940	28940

We also noted that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49977), CMS terminated reclassifications when, as a result of adopting the revised OMB delineations, a hospital's geographic county was reassigned to the CBSA for which it was approved for MGCRB reclassification. At that time, ''home area'' reclassifications were not possible. However, we stated in the proposed rule that since CMS now allows ''home area'' reclassifications, as discussed previously, we would consider this scenario to be a ''home area'' reclassification and we do not believe it is necessary to terminate these reclassifications as we did in FY 2015. We noted that hospitals with a ''home area'' reclassification (or any other form of reclassification) are not eligible to receive an outmigration adjustment determined under section 1886(d)(13) of the Act. We stated in the proposed rule that if such an adjustment is available, a hospital could consider withdrawing or terminating its reclassification by contacting the MGCRB within 45 days of the date the proposed rule was issued in the **Federal Register** (§ 412.273(c)).

We did not receive any comment specific to these proposals. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing these policies as proposed, without modification. The ''home area'' reclassifications listed in Table 3 of this section will be assigned to the revised CBSA listed in column 4 of that table for the remainder of the three year reclassification period.

3. Redesignations Under Section 1886(d)(8)(B) of the Act

a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal

year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act. Because the out-migration adjustment, once finalized, is locked for a 3-year period under section 1886(d)(13)(F) of the Act, the hospital would be eligible to accept its out-migration adjustment in either the second or third year.

b. Effects of Implementation of Revised OMB Labor Market Area Delineations on Redesignations Under Section 1886(d)(8)(B) of the Act

As discussed in section III.A.2. of the preamble of the proposed rule, CMS proposed to update the CBSA labor market delineations to reflect the changes made in the September 14, 2018 OMB Bulletin 18–04. In that section, consistent with the revised OMB delineations, we proposed that 47 currently rural counties be added to new or existing urban CBSAs. We stated in the proposed rule (85 FR 32722) that, of those 47 counties, 23 are currently deemed urban under section 1886(d)(8)(B) of the Act. Hospitals located in such a ''Lugar'' county, barring another form of wage index reclassification, are assigned the reclassified wage index of a designated urban CBSA. Section 1886(d)(8)(B) of the Act defines a deemed urban county as a ''rural county adjacent to one or more urban areas'' that meets certain commuting thresholds. We explained in the proposed rule that since we proposed to modify the status of these 23 counties from rural to urban, they would no longer qualify as ''Lugar'' counties. We further stated that hospitals located within these counties would be considered geographically urban under the revised OMB delineations. In the proposed rule, we provided the following table listing the counties that would no longer be deemed urban under section 1886(d)(8)(B) of the Act if we adopt the revised OMB delineations.

COUNTIES THAT WOULD NO LONGER BE DEEMED URBAN UNDER

1886(d)(8)(B) OF THE ACT DUE TO URBAN GEOGRAPHICAL STATUS

County Name	FIPSCD	Current "Lugar" CBSA	CBSA Name
LEVY	12075	23540	Gainesville, FL
TALBOT	13263	17980	Columbus, GA-AL
PARKE	18121	45460	Terre Haute, IN
WARREN	18171	29200	Lafayette-West Lafayette, IN
BOONE	19015	11180	Ames, IA
JASPER	19099	19780	Des Moines-West Des Moines, IA
ASSUMPTION	22007	12940	Baton Rouge, LA
FRANKLIN	25011	44140	Springfield, MA
IONIA	26067	24340	Grand Rapids-Kentwood, MI
SHIAWASSEE	26155	29620	Lansing-East Lansing, MI
STONE	28131	25060	Gulfport-Biloxi, MS
CAMDEN	37029	47260	Virginia Beach-Norfolk-Newport News, VA-NC
GRANVILLE	37077	20500	Durham-Chapel Hill, NC
HARNETT	37085	39580	Raleigh-Cary, NC
ADJUNTAS	72001	38660	Ponce, PR
LAS MARIAS	72083	32420	Mayagüez, PR
CLARENDON	45027	44940	Sumter, SC
HARRISON	48203	30980	Longview, TX
KING AND QUEEN	51097	40060	Richmond, VA
MADISON	51113	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
SOUTHAMPTON	51175	47260	Virginia Beach-Norfolk-Newport News, VA-NC
JACKSON	54035	16620	Charleston, WV
MORGAN	54065	25180	Hagerstown-Martinsburg, MD-WV

We discuss in section III.A.2.b.ii of this final rule the comments we received related to counties that would no longer be deemed urban under section 1886(d)(8)(B) of the Act. After consideration of the public comments received, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, the proposed list of counties no longer deemed urban under section 1886(d)(8)(B) of the Act.

We noted that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49973 through 49977), when we adopted large scale changes to the CBSA labor market delineations based on the new decennial census, we also re-evaluated the commuting data thresholds for all eligible rural counties in accordance with the methodology set forth in section 1886(d)(8)(B) of the Act. In FY 2015, the OMB bulletin we used to update the CBSA delineations was based on the results of the 2010 decennial census, and had broad ranging nationwide impacts. We stated in the proposed rule (85 FR 32724) that with some exceptions, notably the FY 2020 IPPS/LTCH final rule where we modified the CBSA assignment for some ''Lugar'' counties based on a revised interpretation of the statute (84 FR 42315 through 42318), it has been CMS's long-standing policy to only revise the list of qualifying counties in conjunction with the adoption of the large scale OMB delineation changes following the results of a decennial census. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, as we stated in the proposed rule, the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses. We stated in the proposed rule that although we believe the transition wage index described in section III.B.2.e. of the preamble of this final rule would mitigate significant negative impacts on affected hospitals, and provide hospitals with adequate time to evaluate alternative wage index reclassification options, we were aware that several hospitals in counties that would be considered rural under the revised OMB delineations would qualify for ''Lugar'' status, were CMS to reevaluate the commuting data and new labor market delineations. We stated in the proposed rule that we believe providing Lugar status to these hospitals, as appropriate, would further mitigate any significant negative impacts on affected hospitals. We therefore proposed to reevaluate the ''Lugar'' status for all counties in FY 2021 using the same commuting data table used to evaluate the list of ''Lugar''

counties when CMS adopted new OMB delineations in FY 2015 rulemaking. The data table is the ''2006–2010 5-Year American Community Survey Commuting Flows and Employment'' (available on OMB's website: *https://www.census.gov/data/tables/2010/demo/metro-micro/commuting-employment-2010.html*). As we explained in the proposed rule, since we are using the same data tables, any difference in the list of qualifying counties would be solely due to the effects of the updated OMB delineations. We stated in the proposed rule that we believe making the revisions to the qualifying counties using the updated OMB delineations but the same 2006–2010 commuting data tables used in the FY 2015 IPPS/LTCH PPS final rule strikes an appropriate balance between reserving comprehensive revisions to the list of qualifying counties to instances where we adopt large scale OMB delineation changes following a decennial census, and the desire to mitigate any significant negative impacts on hospitals of the updated OMB delineations (which do contain a number of material changes). We also proposed to use the same methodology discussed in the FY 2020 IPPS/LTCH final rule (84 FR 42315 through 42318) to assign the appropriate reclassified CBSA for hospitals in ''Lugar'' counties. That is, when assessing which CBSA to assign, we stated we would sum the total number of workers that commute from the ''Lugar'' county to both ''central'' and ''outlying'' urban counties (rather than just ''central'' county commuters).

By applying the 2010 ACS commuting data to the updated OMB labor market delineations, we proposed the following changes to the current ''Lugar'' county list. Most notably, we stated in the proposed rule (85 FR 32724) that, based on this commuting data and the revised OMB delineations, all 34 urban counties that became rural under the revised OMB delineations would qualify as ''Lugar'' counties and all hospitals located within them would be designated as ''Lugar.'' We noted that this would affect 10 current hospitals located in those counties. Additionally, due to the change in designation of some urban counties from ''outlying'' to ''central'' status by OMB, we proposed to add two current rural counties in NY as ''Lugar'' counties. Specifically, we stated that hospitals located in Columbia county, NY (FIPSCD 36021) would be deemed ''Lugar'' hospitals and reclassified to urban CBSA 10580 (Albany-Schenectady-Troy, NY) and hospitals located in Sullivan county, NY (FIPSCD 36105) would be deemed ''Lugar'' hospitals and reclassified to urban CBSA 39100 (Poughkeepsie-Newburgh-Middletown, NY). However, we noted that all hospitals in these New York counties currently have MGCRB reclassifications in place for FY 2021, which would supersede these ''Lugar'' reclassifications. Finally, we stated that Calhoun County, TX (FIPSCD 48057) would no longer qualify as a ''Lugar'' county due to the fact it is no longer adjacent to CBSA 18580 (Corpus Christi, TX). We proposed to remove Calhoun County from the list of ''Lugar'' counties. We noted that there are no IPPS hospitals located in Calhoun County.

In the proposed rule, we provided a table listing the proposed revised list of rural counties containing hospitals that would be redesignated as urban under section 1886(d)(8)(B) of the Act (based on the revised OMB delineations and 2010 census data) (see 85 FR 32725 through 32728). We note that this table of ''Lugar'' counties set forth in the proposed rule contained several alignment errors between columns. In some cases, counties were listed as being assigned to an incorrect CBSA number or name. However, the reclassification assignments were correct in the proposed rule wage index tables and those were used for wage index calculations. The final table included in this rule has been corrected.

We did not receive any comments related to the proposed revisions to the list of ''Lugar'' counties. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing the proposed list of rural counties containing hospitals redesignated as urban under section 1886(d)(8)(B) of the Act with modifications to correct the errors discussed previously. The final table is set forth below.

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RURAL COUNTIES CONTAINING HOSPITALS THAT ARE REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT BEGINNING FY 2021 (based on revised OMB delineations and 2010 census data)

Lugar County Name	FIPSCD	CBSA	CBSA Name
CHAMBERS	01017	12220	Auburn-Opelika, AL
CHEROKEE	01019	40660	Rome, GA
CLEBURNE	01029	12060	Atlanta-Sandy Springs-Alpharetta, GA
MACON	01087	12220	Auburn-Opelika, AL
TALLADEGA	01121	13820	Birmingham-Hoover, AL
WALKER	01127	13820	Birmingham-Hoover, AL
DENALI	02068	21820	Fairbanks, AK
HOT SPRING	05059	26300	Hot Springs, AR
LITCHFIELD	09005	35300	New Haven-Milford, CT
BRADFORD	12007	23540	Gainesville, FL
GULF	12045	37460	Panama City, FL
WASHINGTON	12133	37460	Panama City, FL
BAKER	13007	10500	Albany, GA
CHATTOOGA	13055	40660	Rome, GA
JACKSON	13157	12060	Atlanta-Sandy Springs-Alpharetta, GA
LUMPKIN	13187	12060	Atlanta-Sandy Springs-Alpharetta, GA
POLK	13233	12060	Atlanta-Sandy Springs-Alpharetta, GA
PULASKI	13235	47580	Warner Robins, GA
KALAWAO	15005	27980	Kahului-Wailuku-Lahaina, HI
ONEIDA	16071	36260	Ogden-Clearfield, UT
CHRISTIAN	17021	44100	Springfield, IL
DE WITT	17039	14010	Bloomington, IL
FORD	17053	16580	Champaign-Urbana, IL
IROQUOIS	17075	28100	Kankakee, IL
LOGAN	17107	44100	Springfield, IL
MASON	17125	37900	Peoria, IL
OGLE	17141	40420	Rockford, IL

Lugar County Name	FIPSCD	CBSA	CBSA Name
UNION	17181	16060	Carbondale-Marion, IL
CLINTON	18023	29200	Lafayette-West Lafayette, IN
GREENE	18055	14020	Bloomington, IN
HENRY	18065	26900	Indianapolis-Carmel-Anderson, IN
MARSHALL	18099	43780	South Bend-Mishawaka, IN-MI
SCOTT	18143	31140	Louisville/Jefferson County, KY-IN
SPENCER	18147	21780	Evansville, IN-KY
STARKE	18149	23844	Gary, IN
TIPTON	18159	26900	Indianapolis-Carmel-Anderson, IN
WELLS	18179	23060	Fort Wayne, IN
BUCHANAN	19019	47940	Waterloo-Cedar Falls, IA
CEDAR	19031	26980	Iowa City, IA
DELAWARE	19055	20220	Dubuque, IA
IOWA	19095	26980	Iowa City, IA
PLYMOUTH	19149	43580	Sioux City, IA-NE-SD
FRANKLIN	20059	28140	Kansas City, MO-KS
KINGMAN	20095	48620	Wichita, KS
NELSON	21179	31140	Louisville/Jefferson County, KY-IN
TRIMBLE	21223	31140	Louisville/Jefferson County, KY-IN
JEFFRSON DAVIS	22053	29340	Lake Charles, LA
ST. LANDRY	22097	29180	Lafayette, LA
WEBSTER	22119	43340	Shreveport-Bossier City, LA
OXFORD	23017	30340	Lewiston-Auburn, ME
CAROLINE	24011	12580	Baltimore-Columbia-Towson, MD
ALLEGAN	26005	24340	Grand Rapids-Kentwood, MI
BARRY	26015	24340	Grand Rapids-Kentwood, MI
LENAWEE	26091	11460	Ann Arbor, MI
NEWAYGO	26123	24340	Grand Rapids-Kentwood, MI
TUSCOLA	26157	40980	Saginaw, MI
VAN BUREN	26159	28020	Kalamazoo-Portage, MI
GOODHUE	27049	33460	Minneapolis-St. Paul-Bloomington, MN-WI
MEEKER	27093	33460	Minneapolis-St. Paul-Bloomington, MN-WI
RICE	27131	33460	Minneapolis-St. Paul-Bloomington, MN-WI
SIBLEY	27143	33460	Minneapolis-St. Paul-Bloomington, MN-WI
BENTON	28009	32820	Memphis, TN-MS-AR
PEARL RIVER	28109	35380	New Orleans-Metairie, LA
DADE	29057	44180	Springfield, MO
MC DONALD	29119	22220	Fayetteville-Springdale-Rogers, AR
GOLDEN VALLEY	30037	13740	Billings, MT
HAMILTON	31081	24260	Grand Island, NE

Lugar County Name	FIPSCD	CBSA	CBSA Name
OTOE	31131	30700	Lincoln, NE
DOUGLAS	32005	16180	Carson City, NV
LYON	32019	16180	Carson City, NV
MERRIMACK	33013	31700	Manchester-Nashua, NH
LOS ALAMOS	35028	42140	Santa Fe, NM
CAYUGA	36011	45060	Syracuse, NY
COLUMBIA	36021	10580	Albany-Schenectady-Troy, NY
CORTLAND	36023	27060	Ithaca, NY
GENESEE	36037	40380	Rochester, NY
GREENE	36039	10580	Albany-Schenectady-Troy, NY
LEWIS	36049	48060	Watertown-Fort Drum, NY
MONTGOMERY	36057	10580	Albany-Schenectady-Troy, NY
SCHUYLER	36097	27060	Ithaca, NY
SENECA	36099	40380	Rochester, NY
SULLIVAN	36105	39100	Poughkeepsie-Newburgh-Middletown, NY
CASWELL	37033	15500	Burlington, NC
GREENE	37079	24780	Greenville, NC
POLK	37149	43900	Spartanburg, SC
WILSON	37195	40580	Rocky Mount, NC
SIOUX	38085	13900	Bismarck, ND
TRAILL	38097	24220	Grand Forks, ND-MN
ASHTABULA	39007	17460	Cleveland-Elyria, OH
CHAMPAIGN	39021	18140	Columbus, OH
COLUMBIANA	39029	49660	Youngstown-Warren-Boardman, OH-PA
HARRISON	39067	48260	Weirton-Steubenville, WV-OH
PREBLE	39135	19430	Dayton-Kettering, OH
LE FLORE	40079	22900	Fort Smith, AR-OK
CLINTON	42035	48700	Williamsport, PA
FULTON	42057	25180	Hagerstown-Martinsburg, MD-WV
GREENE	42059	38300	Pittsburgh, PA
LAWRENCE	42073	38300	Pittsburgh, PA
SCHUYLKILL	42107	39740	Reading, PA
SUSQUEHANNA	42115	42540	Scranton--Wilkes-Barre, PA
COLLETON	45029	16700	Charleston-North Charleston, SC
LEE	45061	17900	Columbia, SC
MARION	45067	22500	Florence, SC
NEWBERRY	45071	17900	Columbia, SC
UNION	45087	43900	Spartanburg, SC
CUSTER	46033	39660	Rapid City, SD
HICKMAN	47081	34980	Nashville-Davidson--Murfreesboro--Franklin, TN

Lugar County Name	FIPSCD	CBSA	CBSA Name
MEIGS	47121	17420	Cleveland, TN
ARANSAS	48007	18580	Corpus Christi, TX
BLANCO	48031	12420	Austin-Round Rock-Georgetown, TX
BOSQUE	48035	47380	Waco, TX
FANNIN	48147	19124	Dallas-Plano-Irving, TX
GRIMES	48185	26420	Houston-The Woodlands-Sugar Land, TX
HENDERSON	48213	19124	Dallas-Plano-Irving, TX
HILL	48217	23104	Fort Worth-Arlington-Grapevine, TX
HOOD	48221	23104	Fort Worth-Arlington-Grapevine, TX
MILAM	48331	12420	Austin-Round Rock-Georgetown, TX
NEWTON	48351	13140	Beaumont-Port Arthur, TX
SOMERVELL	48425	23104	Fort Worth-Arlington-Grapevine, TX
VAN ZANDT	48467	19124	Dallas-Plano-Irving, TX
WILLACY	48489	15180	Brownsville-Harlingen, TX
BUCKINGHAM	51029	16820	Charlottesville, VA
CAROLINE	51033	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
FLOYD	51063	13980	Blacksburg-Christiansburg, VA
LOUISA	51109	40060	Richmond, VA
ORANGE	51137	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
PAGE	51139	25500	Harrisonburg, VA
SHENANDOAH	51171	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
SURRY	51181	47260	Virginia Beach-Norfolk-Newport News, VA-NC
COLUMBIA	53013	47460	Walla Walla, WA
ISLAND	53029	42644	Seattle-Bellevue-Kent, WA
MASON	53045	36500	Olympia-Lacey-Tumwater, WA
PEND OREILLE	53051	44060	Spokane-Spokane Valley, WA
ROANE	54087	16620	Charleston, WV
GREEN LAKE	55047	22540	Fond du Lac, WI
JEFFERSON	55055	33340	Milwaukee-Waukesha, WI
WALWORTH	55127	33340	Milwaukee-Waukesha, WI
COAMO	72043	41980	San Juan-Bayamón-Caguas, PR
MARICAO	72093	32420	Mayagüez, PR
SALINAS	72123	25020	Guayama, PR

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J. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the

''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new outmigration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FYs 2016 through 2020 IPPS/LTCH PPS final rules (80 FR 49501, 81 FR 56930, 82 FR 38150, 83 FR 41384, and 84 FR 42318 respectively), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FYs 2016 through 2020, and we proposed to use them again for FY 2021. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2021. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2021, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2021, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).) We did not receive any public comments on this proposed policy for FY 2021. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, for FY 2021, we are finalizing our proposal, without modification, to continue using the same policies, procedures, and computations that were used for the FY 2012 outmigration adjustment and that were applicable for FYs 2016 through 2020.

Table 2 associated with this final rule (which is available via the internet on the CMS website) includes the out-migration adjustments for the FY 2021 wage index. In addition, Table 4A associated with this final rule, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' (also available via the internet on the CMS website) consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2021 identified by FIPS county code, the final FY 2021 out-migration adjustment, and the number of years the adjustment will be in effect. We believe this table makes this information more transparent and provides the public with easier access to this information.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

1. Application for Rural Status and Lock-in Date

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for a discussion on our current policy to calculate the rural floor without the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103.

Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) that we believed there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates. Therefore, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (6) to add a lock-in date by which a hospital's application for rural status must be filed in order to be treated as rural in the wage index and budget neutrality calculations for payment rates for the next Federal fiscal year. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41384 through 41386), we changed the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline, the usual public comment deadline for the IPPS proposed rule. We revised § 412.103(b)(6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

The lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41385 through 41386), this lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims will be paid reflecting its rural status beginning on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42322), we noted that if an

application is approved by the CMS Regional Office after our ratesetting ''lock-in date'', the final rule rural wage index value would most likely not include the data for this hospital in the ratesetting calculation. Therefore, we noted that this may incentivize relatively low wage index hospitals to time their applications to avoid reducing the State's rural wage index. These hospitals could then conceivably cancel their rural reclassifications (effective for next FY), and then reapply again after the ''lock date.'' We stated in the FY 2020 IPPS/LTCH PPS final rule that we plan to monitor this situation over the course of FY 2020, and determine if it is necessary to take action to prevent this type of gaming in future rulemaking.

It has come to our attention that hospitals in certain states are indeed timing their rural reclassifications and applications to exploit the rural reclassification process in order to obtain higher wage index values. For example, at least twenty-one hospitals in one state obtained § 412.103 rural reclassifications after the FY 2020 lock-in date, effectively receiving their state's rural wage index without having their wage data included, which would have lowered their State's rural wage index. These hospitals then requested to cancel their § 412.103 rural reclassifications for FY 2021, in accordance with § 412.103(g)(3). Similarly, five hospitals in another state, hospitals with wage data that would have lowered their state's FY 2021 rural wage index, requested to cancel their § 412.103 rural reclassifications for FY 2021, so that the rural wage index would be set using the data of one geographically rural hospital and two hospitals reclassified under § 412.103 that withdrew their MGCRB reclassifications for FY 2021. We will continue to monitor this situation over the course of FY 2021 and may consider proposing in future rulemaking a policy similar to the minimum waiting period at § 412.103(g)(2)(ii) or other necessary actions to prevent this type of gaming.

2. Change to the Regulations To Allow Electronic Submission of Appeals to the Administrator and Copy to CMS

The regulation at § 412.278(b)(1) addresses a hospital's request for the Administrator's review of an MGCRB decision. This regulation currently states that a request for Administrator review filed by facsimile (FAX) or other electronic means will not be accepted. In addition, § 412.278(b)(1) requires a hospital to mail a copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

In the proposed rule (85 FR 32730), we stated that we believe these policies of prohibiting electronic submission of requests for Administrator review and requiring paper copies to be mailed to CMS are outdated and overly restrictive. In the interest of burden reduction and to promote ease of requests, we proposed to eliminate the prohibition on submitting a request by facsimile or other electronic means so that hospitals may also submit requests for Administrator review of MGCRB decisions electronically. In addition, we proposed to require the hospital to submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group. We specified that copies to CMS' Hospital and Ambulatory Policy Group should be submitted via email to *wageindex@cms.hhs.gov*.

Accordingly, we proposed to revise the regulation at § 412.278(b)(1) to read: The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. The hospital must also submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

Comment: Several commenters supported our proposed revisions to the regulation at § 412.278(b)(1).

Response: We appreciate commenters' support of our proposed revisions to § 412.278(b)(1).

After consideration of the public comments received, for the reasons discussed in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposed revisions to the regulation at § 412.278(b)(1) so that hospitals may also submit requests for Administrator review of MGCRB decisions electronically, and must send an electronic copy of the request to CMS's Hospital and Ambulatory Policy Group.

3. Clarification of Applicable Rural Referral Center (RRC) Criteria for Purposes of Meeting Urban to Rural Reclassification at § 412.103(a)(3)

As discussed in section IV.D. of the preamble of this final rule, for purposes of qualifying for RRC classification, a rural hospital that does not meet the bed size requirement at § 412.96(b)(1)(ii) can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). Specifically, a hospital may demonstrate that its case-mix index is at least equal to the national case-mix index value as established by CMS or the median case-mix index value for urban hospitals located in each region, in accordance with § 412.96(c)(1), and that it has a number of discharges at least equal to 5,000 discharges or, if less, the median number of discharges for urban hospitals located in each region, in accordance with § 412.96(c)(2). CMS publishes the national and regional case-mix index values and the national and regional number of discharges for the purpose of these criteria in the annual notice of prospective payment rates published in the **Federal Register**.

For purposes of qualifying for urban to rural reclassification under § 412.103, a hospital can demonstrate that it would qualify as a rural referral center as set forth in § 412.96, if the hospital were located in a rural area. This condition is set forth at § 412.103(a)(3).

It has come to our attention that there is some confusion regarding which fiscal year's published case mix index (CMI) or numbers of discharges criteria would be used in the situation where a hospital is seeking to meet the urban to rural reclassification criterion at § 412.103(a)(3) by meeting the alternative criteria at § 412.96(c): (1) The criteria published in the final rule in effect on the filing date of the hospital's § 412.103 application, or (2) the criteria that would be in effect during the fiscal year that any RRC classification would become effective (that is, the beginning of the hospital's cost reporting period).

Therefore, we are clarifying that for purposes of meeting the urban to rural reclassification criterion at § 412.103(a)(3), the appropriate CMI values and numbers of discharges to demonstrate RRC eligibility are those published in the IPPS/LTCH PPS final rule in effect as of the filing date (that is, the effective date) of the hospital's application for reclassification under § 412.103. For purposes of RRC classification under § 412.96(c), the appropriate CMI values and numbers of discharges are those published in the IPPS/LTCH PPS final rule in effect when the RRC classification will be effective at the start of the hospital's next cost reporting period, consistent with § 412.96(h)(3) and (i)(3).

For example, Hospital A has a cost reporting period beginning October 1. It applies on September 1, 2020 for urban to rural reclassification under § 412.103(a)(3) and for RRC status, by meeting the alternative criteria at § 412.96(c). For Hospital A's urban to rural reclassification request, the appropriate national or regional CMI

value and number of discharges that the hospital must meet or exceed are the values published in the FY 2020 IPPS/LTCH PPS Final Rule since that is the rule in effect as of the filing date (that is, effective date) of Hospital A's urban to rural reclassification application. For the RRC classification request, the appropriate national or regional CMI value and number of discharges that the hospital must meet or exceed are the values published in the FY 2021 IPPS/LTCH PPS final rule since that is the rule that will be in effect when the RRC classification will become effective at the start of the hospital's next cost reporting period. We note that this policy applies regardless of whether a hospital seeks only § 412.103 rural reclassification, or § 412.103 rural reclassification along with RRC classification.

We believe our policy is appropriate considering that a hospital may apply for rural reclassification under § 412.103 at any time, as previously discussed in section III.K.1. of the preamble of this final rule. We clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38151) that while applications for RRC status must be submitted during the last quarter of a hospital's cost reporting period in accordance with section 1886(d)(5)(C)(i) of the Act, applications for rural reclassification may be submitted at any time, including applications of hospitals seeking rural reclassification under § 412.103(a)(3). A hospital is permitted at any time to submit an urban to rural reclassification request on the basis of qualifying for RRC status under § 412.103(a)(3), even before the publication of the CMI and discharge criteria in the IPPS/LTCH PPS final rule for the period in which any RRC classification would be effective (that is, the start of the hospital's next cost reporting period). We did not receive any comments on this clarification.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files and the preliminary CY 2016 occupational mix data files for the proposed FY 2021 wage index were made available on May 17, 2019 through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2021-Wage-Index-Home-Page*.

On January 31, 2020, we posted a public use file (PUF) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2021-Wage-Index-Home-Page* containing FY 2021 wage index data available as of January 30, 2020. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2016 through September 30, 2017; that is, FY 2017 wage data), a tab with the occupational mix data (which includes data from the CY 2016 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 31, 2020 wage data PUF, and a tab containing the CY 2016 occupational mix data of the hospitals deleted from the January 31, 2020 occupational mix PUF. In a memorandum dated January 29, 2020, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 31, 2020 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2021 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated April 29, 2019, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2016 occupational mix survey data files posted on May 17, 2019, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 17, 2019 preliminary wage and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 3, 2019. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. November 15, 2019 was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 5, 2019 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2020. CMS published the wage index PUFs that included hospitals' revised wage index data on January 31, 2020. Hospitals had until February 14, 2020, to submit requests to the MACs to correct errors in the January 31, 2020 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 31, 2020 PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 14, 2020 for the FY 2021 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 19, 2020. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 2, 2020. Data that were incorrect in the preliminary or January 31, 2020 wage index data PUFs, but for which no correction request was received by the February 14, 2020 deadline, are not considered for correction at this stage. In addition, April 2, 2020 was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 31, 2020 PUF and at least 14 calendar days prior to April 2, 2020 (that is, March 19, 2020), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 2, 2020 for the FY 2021 wage index). We refer readers to the wage index timeline for complete details.

Hospitals were given the opportunity to examine Table 2 associated with the proposed rule, which was listed in

section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2021-IPPS-Proposed-Rule-Home-Page.html*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2017 data used to construct the proposed FY 2021 wage index. We noted in the proposed rule (85 FR 32731) that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2020.

We posted the final wage index data PUFs on April 30, 2020 via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2021-Wage-Index-Home-Page*. The April 2020 PUFs were made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 19, 2020, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2020 wage index data PUFs, changes to the wage and occupational mix data could only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 19, 2020.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 31, 2020 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2020 final wage index data PUFs, a hospital believed that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital was given the opportunity to notify both its MAC and CMS regarding why the hospital believed an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC so that it was received no later than May 29, 2020. May 29, 2020 was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified on or after 13 calendar days prior to April 2, 2019 (that is, March 20, 2020), and at least 14 calendar days prior to May 29, 2020 (that is, May 15, 2020), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 29, 2020 (that is, May 16, 2020) may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2021 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY-2021-Hospital-Wage-Index-Development-Time-Table.pdf*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely (that is, by May 29, 2020) by CMS and the MACs were incorporated into the final FY 2021 wage index, which will be effective October 1, 2020.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2021 payment rates. Accordingly, hospitals that did not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2020, they had the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2021 wage index by September 2020, and the implementation of the FY 2021 wage index on October 1, 2020. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 29, 2020, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 29, 2020 for the FY 2021 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the

correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 29, 2020 deadline for the FY 2021 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 29, 2020 deadline for the FY 2021 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 31 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.L.1. of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 31 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS will correct that data error and the hospital's average hourly wage will likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 31 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 31 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described

earlier and in the FY 2021 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

3. Update to Wage Index Development Timetable To Include Time Zone for Deadlines

During the FY 2021 wage index development process, we received inquiries regarding the time zone for deadlines in the Wage Index Development Timetable. Specifically, hospitals asked if revision requests submitted after 11:59 p.m. Eastern Standard Time (EST) could be accepted if the deadline had not yet passed in the time zone where the hospitals are located. The current timetable does not specify time zones. To eliminate confusion and promote clear deadlines, we proposed to use Eastern Standard Time (EST) as the time zone for wage index deadlines after October 1, 2020 on the FY 2022 Wage Index Development Timetable. We stated in the proposed rule (85 FR 32733) that we believe using one time zone is important for a clear and consistent deadline for all hospitals. We further stated that we also believe that EST is an appropriate time zone for the deadline because CMS's central office headquarters are located in the EST time zone and because it is consistent with the time zone used for other CMS deadlines, such as the deadline to register to report certain quality data via the CMS Web Interface (see the Registration Guide available for download at *https://qpp.cms.gov/mips/how-to-register-for-CMS-WI-and-CAHPS*) and applications for ACOs to participate in the Shared Savings Program (see deadlines outlined at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/for-acos/application-types-and-timeline,* in accordance with § 425.202). We welcomed commenters' input on which time zone is most reasonable for all hospitals and appropriate for supporting consistent, clear deadlines.

We did not receive any comments on our proposal. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing, without modification, our proposal to use Eastern Standard Time (EST) as the time zone for wage index deadlines after October 1, 2020 on the FY 2022 Wage Index Development Timetable.

M. Labor-Related Share for the FY 2021 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we rebased and revised the hospital market basket. We established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, we finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. In addition, in FY 2018, we implemented this revised and rebased labor-related share in a budget neutral manner (82 FR 38522). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325), for FY 2020, we continued to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2019.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32734), for FY 2021, we did not propose to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, professional fees: Labor-related, administrative and facilities support services, installation, maintenance, and repair services, and all other labor-related services. Therefore, for FY 2021, we proposed to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2020.

As discussed in section IV.B. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2021, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

We did not receive any public comments on our proposals related to the labor-related share percentage. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing our proposals, without

modification, to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2020 for all hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.0000.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2021 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflect the national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2021, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2021, we are applying the wage index to a labor-related share of 68.3 percent of the national standardized amount.

IV. Other Decisions and Changes to the IPPS for Operating System

A. Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute directs us to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, effective for discharges occurring on or after October 1, 2018, if a discharge is assigned to one of the MS–DRGs subject to the postacute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge is subject to payment as a transfer case. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018 as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment. Consistent with our policy for other qualified discharges, CMS claims processing software has been revised to identify cases in which hospice benefits were billed on the date of hospital discharge without the appropriate discharge status code. Such claims will be returned as unpayable to the hospital and may be rebilled with a corrected discharge code.

2. Changes for FY 2021

As discussed in section II.F. of the preamble of the FY 2021 IPPS/LTCH PPS final rule, based on our analysis of FY 2019 MedPAR claims data, we proposed to make changes to a number of MS–DRGs, effective for FY 2021. Specifically, we proposed to do the following:

- Reassign procedure codes from MS–DRG 16 (Autologous Bone Marrow

Transplant with CC/MCC or T-Cell Immunotherapy) to create new MS–DRG 18 (Chimeric Antigen Receptor [CAR] T-cell Immunotherapy) for cases reporting the administration of CAR T-cell therapy.

- Create new MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis).
- Reassign procedures involving head, face, neck, ear, nose, mouth, or throat by creating six new MS–DRGs 140–142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and 143–145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and deleting MS–DRGs 129–130 (Major Head and Neck Procedures with CC/MCC or Major Device, and without CC/MCC, respectively, MS–DRGs 131–132 (Cranial and Facial Procedures with CC/MCC and without CC/MCC, respectively) and MS–DRGs 133–134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively).
- Reassign procedure codes from MS–DRGs 469–470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement, and without MCC, respectively) and create two new MS–DRGs, 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) for cases reporting a hip replacement procedure with a principal diagnosis of a hip fracture.
- Reassign procedure codes from MS–DRG 652 (Kidney Transplant) into two new MS–DRGs, 650 and 651 (Kidney Transplant with Hemodialysis with MCC and without MCC, respectively) for cases reporting hemodialysis with a kidney transplant during the same admission.

As discussed in the proposed rule, in light of the proposed changes to these MS–DRGs for FY 2021, according to the regulations under § 412.4(d), we evaluated these MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2019 MedPAR file. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to assess new MS–DRGs and reassess revised MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. We noted that MS–DRGs 469 and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement, and without MCC, respectively) are currently subject to the postacute care transfer policy, and as proposed to be revised, would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. Proposed new MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) would also qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We therefore proposed to add MS–DRGs 521 and 522 to the list of MS–DRGs that are subject to the postacute care transfer policy. We noted that MS–DRGs that are subject to the postacute transfer policy for FY 2020 and are not revised will continue to be subject to the policy in FY 2021. We note that, as discussed in section II. of this final rule, we are finalizing these proposed changes to the MS–DRGs.

Using the March 2020 update of the FY 2019 MedPAR file, we developed the following updated chart which sets forth the analysis of the postacute care transfer policy criteria completed for this final rule with respect to each of these new or revised MS–DRGs. We note that this chart is updated from the MedPAR file used in the proposed rule (the December 2019 update of the FY 2019 MedPAR file).

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LIST OF NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2021

New or Revised MS-DRGs	MS-DRG Title	Total Cases	Postacute Care Transfers (55th percentile: 1,387)	Short-Stay Postacute Care Transfers	Percent of Short-Stay Postacute Care Transfers to all Cases (55th percentile: 9.3237%)	Current Postacute Care Transfer Policy Status	Proposed Postacute Care Transfer Policy Status
016	Autologous Bone Marrow Transplant with CC/MCC	2,132	475*	141	6.6604*	No	No
018	Chimeric Antigen Receptor (CAR) T-Cell Immunotherapy	313	84*	18	0.0575*	New	No
019	Simultaneous Pancreas and Kidney Transplant with Hemodialysis	86	32*	14	16.279	New	No
140	Major Head and NeckProcedures with MCC	656	379*	96	14.634	New	No
141	MajorHead and Neck Procedures with CC	2,499	798*	82	3.2412*	New	No
142	Major Head and Neck Procedures without CC/MCC	1,373	220*	20	1.4566*	New	No
143	Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC	760	356*	37	9.6052	New	No
144	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC	1,599	458*	67	4.1901*	New	No
145	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC	1,090	141*	0	0*	New	No
469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement	12,312	8,246	1484	12.004	Yes	Yes
470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC	359,626	224,025	0	0*	Yes	Yes**
521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC	14,991	13,460	5834	38.970	New	Yes
522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC	50,347	45,958	15,908	31.662	New	Yes
650	Kidney Transplant with Hemodialysis with MCC	2,557	743*	200	7.7043*	New	No
651	Kidney Transplant with Hemodialysis without MCC	1,156	349*	74	6.4013*	New	No
652	Kidney Transplant	9,193	1,879	346	3.8725*	No	No

* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG will all qualify under the postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

Based on our annual review of proposed new or revised MS–DRGs and analysis of the December 2019 update of the FY 2019 MedPAR file, we identified MS–DRGs that we proposed to include on the list of MS–DRGs subject to the special payment policy methodology. Based on our analysis of proposed changes to MS–DRGs included in the proposed rule, we determined that MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) would meet the criteria for the MS–DRG special payment methodology. Therefore, we proposed that MS–DRGs 521 and 522 would be subject to the MS–DRG special payment methodology, effective FY 2021. The following table include updates from the March 2020 update of the FY 2019 MedPAR file.

LIST OF NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2021

Revised MS-DRG	MS-DRG Title	Geometric Mean Length of Stay	Average Charges of 1-Day Discharges	50 Percent of Average Charges for all Cases within MS-DRG	Current Special Payment Policy Status	Special Payment Policy Status
469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement	3.1133*	$83,390	$51,452	No	No
470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC	1.7753*	$59,910	$31,995	No	No
521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC	6.1686	$54,106	$51,978	New	Yes
522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC	4.0993	$66,939	$37,652	New	Yes

* Indicates a special payment policy criterion that the MS-DRG did not meet.

Comments: A commenter urged CMS not include MS–DRGs 521 and 522 on the list of MS–DRGs that are subject to the postacute care transfer policy. The commenter asserted that adding these new MS–DRGs to the postacute care transfer policy will incentivize short-term acute care hospitals to keep hip replacement patients longer so that the patient does not receive care from a postacute care provider, potentially leading to adverse health impacts to vulnerable beneficiaries.

Response: We disagree that the postacute care transfer policy creates an incentive to keep patients in the hospital longer than necessary. Our longstanding view is the policy addresses the appropriate level of payment once clinical decisions about the most appropriate care in the most appropriate setting have been made. We also note that the procedure codes proposed to be assigned to MS–DRGs 521 and 522 are currently assigned to MS–DRGs 496 and 470, which currently are subject to the postacute care transfer policy.

After consideration of the comments we received, we are finalizing our proposal to add MS–DRGs 521 and 522 to the list of MS–DRGs that are subject to the postacute care transfer policy and the MS DRG special payment methodology for FY 2021.

The postacute care transfer and special payment policy status of these MS–DRGs is reflected in Table 5 associated with this final rule, which is listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

B. Changes in the Inpatient Hospital Update for FY 2021 (§ 412.64(d))

1. FY 2021 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2021, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2020. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2021 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero.

In compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating market basket with the rebased and revised 2014-based IPPS operating market basket, effective with FY 2018.

We proposed to base the proposed FY 2021 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2019 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2019, which was estimated to be 3.0 percent. We also proposed that if more recent data

subsequently become available (for example, a more recent estimate of the market basket and the MFP), we would use such data, if appropriate, to determine the FY 2021 market basket update and the MFP adjustment in the final rule.

For this final rule, based on IGI's second quarter 2020 forecast with historical data through the first quarter of 2020, the FY 2021 growth rate of the 2014-based IPPS market basket is estimated to be 2.4 percent. We note that the fourth quarter 2019 forecast used for the proposed market basket update was developed prior to the economic impacts of the COVID–19 pandemic. This lower update (2.4 percent) for FY 2021 relative to the proposed rule (3.0 percent) is primarily driven by slower than anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.

For FY 2021, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed an MFP adjustment of 0.4 percentage point. Similar to the market basket update, for the proposed rule, we used IGI's fourth quarter 2019 forecast of the MFP adjustment to compute the proposed FY 2021 MFP adjustment. As noted previously, we proposed that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2021 market basket update and the MFP for the final rule.

Based on the more recent data available for this final rule, the current estimate of the 10-year moving average growth of MFP for FY 2021 is -0.1 percentage point. This MFP is based on the most recent macroeconomic outlook from IGI at the time of rulemaking (released June 2020) in order to reflect more current historical economic data. IGI produces monthly macroeconomic forecasts, which include projections of all of the economic series used to derive MFP. In contrast, IGI only produces forecasts of the more detailed price proxies used in the 2014-based IPPS market basket on a quarterly basis. Therefore, IGI's second quarter 2020 forecast is the most recent forecast of the 2014-based IPPS market basket increase.

We note that it has typically been our practice to base the projection of the market basket price proxies and MFP in the final rule on the second quarter IGI forecast. For this final rule, we are using the IGI June 2020 macroeconomic forecast for MFP because it is a more recent forecast, and it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. Historically, the MFP adjustment based on the second quarter IGI forecast has been very similar to the MFP adjustment derived with IGI's June macroeconomic forecast. Substantial changes in the macroeconomic indicators in between monthly forecasts are atypical.

Given the unprecedented economic uncertainty as a result of the COVID–19 pandemic, the changes in the IGI macroeconomic series used to derive MFP between the IGI second quarter 2020 forecast and the IGI June 2020 macroeconomic forecast are significant. Therefore, we believe it is appropriate to use IGI's more recent June 2020 macroeconomic forecast to determine the MFP adjustment for the final rule as it reflects more recent historical data. For comparison purposes, the 10-year moving average growth of MFP for FY 2021 is projected to be -0.1 percentage point based on IGI's June 2020 macroeconomic forecast compared to the 10-year moving average growth of MFP for FY 2021 of 0.7 percentage point based on IGI's second quarter 2020 forecast. Mechanically subtracting the negative 10-year moving average growth of MFP from the hospital market basket percentage increase using the data from the IGI June 2020 macroeconomic forecast would have resulted in a 0.1 percentage point increase in the FY 2021 market basket update. However, under section 1886(b)(3)(B)(xi)(I) of the Act, the Secretary is required to reduce (not increase) the hospital market basket percentage increase by changes in economy-wide productivity. Accordingly, we are applying a 0.0 MFP adjustment to the FY 2021 market basket percentage increase.

Comment: A commenter appreciated the proposed inpatient hospital update. We also received a comment recommending that CMS not use market basket data that had been updated through March 2020, given the significant economic disruption and effects of the pandemic-driven shutdown, to ensure that the market basket update accurately reflects the higher costs incurred by hospitals during the pandemic. This same commenter urged CMS to ensure the underlying data, for market basket and other policies, is most appropriately selected to hold hospitals harmless against the unprecedented impacts of COVID–19.

Response: We appreciate the commenters' support and input on the proposal. As previously discussed, for this final rule we are using a more recent forecast available, because it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. For this final rule, we are finalizing a market basket update of 2.4 percent based on

IHS Global Inc.'s second-quarter 2020 forecast (with historical data through the first-quarter 2020) and an MFP adjustment of 0.0 percentage point, as discussed earlier.

Based on these most recent data available, we have determined four applicable percentage increases to the standardized amount for FY 2021, as specified in the following table:

FY 2021 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.6	-0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.8	0	-1.8
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	0.0	0.0	0.0	0.0
Applicable Percentage Increase Applied to Standardized Amount	**2.4**	**0.6**	**1.8**	**0.0**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. (Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).)

For FY 2021, we proposed the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.6 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 1.85 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of 0.35 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of -0.4 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As noted previously, for the FY 2021 IPPS/LTCH PPS proposed rule, we used IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket update with historical data through third quarter 2019. Similarly, we used IGI's fourth quarter 2019 forecast of the MFP adjustment. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket increase and the MFP), we would use such data, if appropriate, to determine the update in the final rule.

We did not receive any public comments on our proposal. Therefore, we are finalizing the proposal to determine the update to the hospital-specific rates for SCHs and MDHs in this final rule using the most recent available data, as previously discussed.

For this final rule, based on the most recent available data, we are finalizing the following updates to the hospital specific rates applicable to SCHs and MDHs: An update of 2.4 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.8 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of 0.6 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of 0.0 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2021 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56937 through 56938), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to determine an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this final rule. Accordingly, in the FY 2021 IPPS/LTCH PPS proposed rule, for FY 2021, we proposed an applicable percentage increase of 2.6 percent to the standardized amount for hospitals located in Puerto Rico.

We did not receive any public comment on our proposal with respect to the Puerto Rico hospital update.

Based on the most recent data available for this final rule (as discussed previously in section IV.B.1. of the preamble of this final rule), we are finalizing an applicable percentage increase of 2.4 percent to the standardized amount for hospitals located in Puerto Rico. We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico. In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2021.

C. Amendment To Address Short Cost Reporting Periods During Applicable Timeframe for Establishment of Service Area for Sole Community Hospitals Under § 412.92(c)(3)

Sections 1886(d)(5)(D) and (d)(5)(G) of the Act provide special payment protections under the IPPS to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs), respectively. Section 1886(d)(5)(D)(iii) of the Act defines an SCH in part as a hospital that the Secretary determines is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 43897).

The criteria to be classified as an SCH are set forth at 42 CFR 412.92(a). Under the criteria at 42 CFR 412.92(a)(1)(i) and (ii), CMS classifies a hospital as a sole community hospital if it is located: (1) In a rural area; and (2) between 25 and 35 miles from other like hospitals and meets one of the following criteria:

- No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area.
- The hospital has fewer than 50 beds and the MAC certifies that the hospital would have met the previously discussed criteria were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital.

The term ''service area'' is defined under the regulations at 42 CFR 412.92(c)(3) as the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital. For more information on service areas, we refer readers to the FY 2002 IPPS final rule (66 FR 39875).

We have become aware of some situations where a hospital's most recent cost reporting period prior to seeking SCH classification is a short cost reporting period (that is, less than a 12-month cost reporting period). Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32740), we proposed to amend § 412.92(c)(3) to clarify our policy in this situation. Specifically, we proposed to amend § 412.92(c)(3) to reflect that where the hospital's cost reporting period ending before it applies for classification as a sole community hospital is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used. We noted that this policy is consistent with our policy for determining Medicare utilization for purposes of MDH classification, as reflected in the regulations at 42 CFR 412.108(a)(1)(v). We invited public comment on our proposed amendment to § 412.92(c)(3).

We did not receive any public comments on our proposed amendment to § 412.92(c)(3). Therefore, we are finalizing our proposal as previously described, without modification.

D. Rural Referral Centers (RRCs)—Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for

urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and

- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2021 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2021 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These values are based on discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019), and include bills posted to CMS' records through March 2020.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32741), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, they must have a CMI value for FY 2019 that is at least—

- 1.70435 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in a table in the proposed rule (85 FR 32741). We stated in the proposed rule that we intended to update the proposed CMI values in the FY 2021 final rule to reflect the updated FY 2019 MedPAR file, which will contain data from additional bills received through March 2020.

We did not receive any public comments on our proposals.

Based on the latest available data (FY 2019 bills received through March 2020), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, they must have a CMI value for FY 2019 that is at least:

- 1.7049 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the following table.

Region	Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4447
2. Middle Atlantic (PA, NJ, NY)	1.5005
3. East North Central (IL, IN, MI, OH, WI)	1.60875
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.62455
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5777
6. East South Central (AL, KY, MS, TN)	1.54085
7. West South Central (AR, LA, OK, TX)	1.74375
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7833
9. Pacific (AK, CA, HI, OR, WA)	1.6913

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32741), for FY 2021, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018 (that is, October 1, 2017 through September 30, 2018), which were the latest cost report data available at the time the proposed rule was developed. Therefore, we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, must have, as the number of discharges for its cost reporting period that began during FY 2018, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2021 IPPS/LTCH PPS proposed rule at 85 FR 32742). In the proposed rule, we stated that we intended to update these numbers in the FY 2021 final rule based on the latest available cost report data.

We did not receive any public comments on our proposals.

Based on the latest discharge data available at this time, that is, for cost reporting periods that began during FY 2018, the final median number of discharges for urban hospitals by census

region are set forth in the following table.

Region	Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,611
2. Middle Atlantic (PA, NJ, NY)	10,231
3. East North Central (IL, IN, MI, OH, WI)	8,624
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,647
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,607
6. East South Central (AL, KY, MS, TN)	9,134
7. West South Central (AR, LA, OK, TX)	6,002
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,682
9. Pacific (AK, CA, HI, OR, WA)	8,990

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

a. Amendment to § 412.96(c)(2) for Hospital Cost Reporting Periods That Are Longer or Shorter Than 12 Months

As previously noted, in addition to meeting other criteria, to qualify for initial RRC status for cost reporting periods beginning on or after October 1 of a given fiscal year, under § 412.96(c)(2), a hospital must meet the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. We typically use the cost reporting periods that are 3 years prior to the fiscal year for which a hospital is seeking RRC status to compute the regional median discharges, as these are generally the latest cost report data available at the time of the development of the proposed and final rules. For example, and as discussed previously, for FY 2021, we are updating the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018.

We have become aware of situations where a hospital's cost reporting period that began during the fiscal year used to compute the regional median discharge values for a given fiscal year is a short cost reporting period (that is, less than 12 months) and as a result, the provider may not meet the minimum discharges requirement. Conversely, there may also be situations where a hospital's cost reporting period that began during the fiscal year used to compute the regional median discharge values for a given fiscal year is a long cost reporting period (that is, greater than 12 months). In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32742), we proposed to amend the RRC regulations to add a new paragraph (c)(2)(iii) to § 412.96 stating that if the hospital's cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges is for less than 12 months or longer than 12 months, the hospital's number of discharges for that cost reporting period will be annualized to estimate the total number of discharges for a 12 month cost reporting period. We stated that we believe this policy, which is generally consistent with how we have addressed short cost reporting periods for purposes of determining discharges for RRC status in the past, provides a more uniform treatment among hospitals for purposes of determining the number of discharges for those hospitals for which the applicable cost reporting period is shorter or longer than 12 months. We proposed that to annualize the discharges, the MAC would divide the discharges by the number of days in the hospital's cost reporting period and then multiply by the length of a full year (365 or 366 calendar days, as applicable) to estimate the total number of discharges for a 12-month cost reporting period. For example, a short cost reporting period beginning on January 1 and ending on October 31 that is 10 months (or 304 days) with 4,200 discharges would be annualized in a non-leap year as follows: $(4{,}200 \div 304) \times 365 = 5{,}043$ discharges annualized. Under this proposal, if the hospital has multiple cost reports beginning in the same fiscal year and none of those cost reports are for 12 months, the hospital's number of discharges in the hospital's longest cost report beginning in that fiscal year would be annualized to estimate the total number of discharges for a 12 month cost reporting period. We invited public comment on our proposed annualization methodology and our proposed amendment to § 412.96(c)(2).

Comments: A few commenters supported the annualization of discharges in a long or short cost reporting period for purposes of determining a hospital's eligibility for RRC classification.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal as previously described, without modification.

E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total

per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. (Section 50204 also extended prior changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals through FY 2018.) Currently, the low-volume hospital qualifying criteria provide that a hospital must have fewer 3,800 total discharges during the fiscal year, and the hospital must be located more than 15 road miles from the nearest ''subsection (d)'' hospital. These criteria will remain in effect through FY 2022. Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Therefore, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2022, it must have fewer than 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the **Federal Register** on April 26, 2018 (83 FR 18301 through 18308).)

2. Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2019 Through 2022

As discussed earlier, section 50204 of the Bipartisan Budget Act of 2018 further modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), to implement this requirement, we specified a continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment for FYs 2019 through 2022 is calculated using the following formula:

Low-Volume Hospital Payment Adjustment = $0.25 - [0.25/3300] \times$ (number of total discharges $- 500$) = $(95/330) -$ (number of total discharges/13,200).

For this purpose, we specified that the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment for FYs 2019 through 2022 is set forth in the regulations at 42 CFR 412.101(c)(3).

3. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking (for example, the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and § 412.101(b)(2)(iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine

if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2021, as was the case for FYs 2019 and 2020, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

We discussed in the proposed rule that in accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). We stated that for a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2021, we proposed that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Consistent with historical practice, for FY 2021, we proposed that a hospital's written request must be received by its MAC no later than September 1, 2020 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2020. If a hospital's written request for low-volume hospital status for FY 2021 is received after September 1, 2020, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, we stated that the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2021 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination. We noted in the proposed rule that this proposal was consistent with the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2020 (84 FR 42348 through 42349).

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2020 may continue to receive a low-volume hospital payment adjustment for FY 2021 without reapplying if it continues to meet the applicable mileage and discharge criteria (which, as discussed previously, are the same qualifying criteria that apply for FY 2020). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2021. (Determination of meeting the discharge criterion is discussed earlier in this section.) We noted in the proposed rule that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275). Consistent with historical policy, a hospital must submit its request, including this written verification, for each fiscal year for which it seeks to receive the low-volume hospital payment adjustment, and in accordance with the timeline described earlier.

Comments: We received comments expressing continued support of the low-volume hospital adjustment changes included in the Bipartisan Budget Act of 2018.

Response: While these changes are statutory, we appreciate commenters' support.

As discussed in section I.A.2 of this FY 2021 IPPS/LTCH PPS final rule, we are waiving the delayed effective date for this final rule. The proposed deadline of September 1, 2020 for receipt of a hospital's written request by its MAC in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2020, may occur very near or on the date of issuance of this final rule. Due to this unique circumstance, in this final rule we are modifying the proposed deadline to September 15, 2020. Accordingly, for FY 2021, we are establishing that a hospital's written request must be received by its MAC no later than September 15, 2020 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2020. If a hospital's written request for low-volume hospital status for FY 2021 is received after September 15, 2020, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2021 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

F. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2021,

the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2021 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

We did not receive any comments regarding the IME adjustment factor, which, as noted earlier, is statutorily required. Accordingly, for discharges occurring during FY 2021, the IME formula multiplier is 1.35.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2021 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this final rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus statutory adjustment of 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all

hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In this FY 2021 IPPS/LTCH PPS final rule, we discuss our specific policies regarding eligibility to receive empirically justified Medicare DSH payments and uncompensated care payments for FY 2021 with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology at section 1886(r) (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2021, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- *Sole community hospitals* (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final

determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a Factor 3 and an uncompensated care payment amount for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator of Factor 3 of the uncompensated care payment methodology will be based only on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.

- *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced Initiative (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at: *https://innovation.cms.gov/initiatives/bpci-advanced/.*
- *IPPS hospitals that are participating in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments.
- *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. At the time of issuance of this final rule, there are 22 hospitals that will be participating in the demonstration program in FY 2021. Under the payment methodology that applies during the second 5 years of the extension period under the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

Comment: A commenter stated that their hospital has recently submitted its fiscal year end 12/31/2019 cost report and that due to the Medicaid Expansion in their respective state, the hospital believed it would qualify for DSH and uncompensated care payments in FY 2021 based on the information reflected in this submission. However, the commenter noted that the FY 2021 NPRM DSH Public Use File lists the hospital as a ''No'' in the column for projected DSH eligibility because the data used in the proposed rule was based on a cost report year pre-Medicaid expansion. The commenter asks CMS to consider updating their hospital's DSH eligibility status and using its recently submitted as-filed cost report in the final rule's FY 2021 DSH PUF File for purposes of projected DSH eligibility.

Response: The regulation located at 42 CFR 412.106 governs eligibility for the Medicare DSH payment adjustment and specifies how the disproportionate patient percentage is calculated. The DSH public use file does not determine DSH eligibility. A hospital's eligibility to receive empirically justified DSH payments, can change throughout the year as the MACs receive and review updated data.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this final rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2020, and the policies we are finalizing for FY 2021.

a. Calculation of Factor 1 for FY 2021

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for

a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2020, in this FY 2021 IPPS/LTCH PPS final rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2021, we proposed to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to the publication of our final projections in this FY 2021 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of Factor 1 for FY 2021 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this final rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on the Office of the Actuary's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2018 through FY 2021 are discussed in the table titled ''Factors Applied for FY 2018 through FY 2021 to Estimate Medicare DSH Expenditures Using FY 2017 Baseline.''

For purposes of calculating our proposal for Factor 1 and modeling the impact of the FY 2021 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's December 2019 Medicare DSH estimates, which were based on data from the September 2019 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2020 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2020 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the December 2019 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's December 2019 Medicare DSH estimates. The 27 hospitals that were then participating in the Rural Community Hospital Demonstration Program were also excluded from these estimates because, under the payment methodology that applies during the second 5 years of the extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For the proposed rule, using the data sources as previously discussed, the Office of the Actuary's December 2019 estimate for Medicare DSH payments for FY 2021 without regard to the application of section 1886(r)(1) of the Act, was approximately $14.004 billion. Therefore, also based on the December 2019 estimate, the estimate of empirically justified Medicare DSH payments for FY 2021, with the application of section 1886(r)(1) of the Act, was approximately $3.840 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2021). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in the proposed rule, we proposed that Factor 1 for FY 2021 would be $ 11,518,901,035.84, which was equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2021 ($15,358,534,714.46 minus $3,839,633,678.61). In the FY 20201 IPPS/LTCH PPS proposed rule (85 FR 32748), we noted that consistent with our approach in previous rulemakings, OACT intended to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2021 IPPS/LTCH PPS final rule.

We noted in the FY 2021 IPPS/LTCH PPS proposed rule, that the Factor 1 estimates for final rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the OMB website at: *https://www.whitehouse.gov/omb/budget*. We recognized that our reliance on the economic assumptions and actuarial analysis used to develop the President's Budget in estimating Factor 1 has an impact on stakeholders who wish to replicate the Factor 1 calculation, such as modelling the relevant Medicare Part A portion of the budget, but indicated that we believe commenters are able to meaningfully comment on our estimate of Factor 1 without replicating the President's Budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we referred readers to the ''2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/*

index.html?redirect=/reportstrustfunds/ under ''Downloads.'' We noted that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

In the FY 2021 IPPS/LTCH PPS proposed rule, we referred readers to the 2017 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections. (available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*).

Comment: As in previous years, a common concern and/or request expressed by some commenters was the need for greater transparency in the methodology used by CMS and OACT to calculate Factor 1; several commenters specifically requested that a detailed description of the methodology be made public. In relation to this, a commenter asserted that the lack of opportunity afforded to hospitals to review the data used in rulemaking is in violation of the Administrative Procedure Act and expressed concerns about the lack of transparency in how Factor 1 is calculated, arguing that hospitals cannot meaningfully comment on the methodology given the lack of details. In particular, this commenter asserted that the proposed rule neither explained the assumption that Medicaid expansion would draw enrollees who are healthier than the average Medicaid beneficiary and, by extension, would have fewer hospital visits, nor described the data CMS used in making this assumption.

Response: We thank the commenters for their input. We disagree with commenters' assertion regarding the lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. As explained in the FY 2021 IPPS/LTCH PPS proposed rule, and in this section of this final rule, we have been and continue to be transparent about the methodology and data used to estimate Factor 1. Regarding the commenters who reference the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2021 IPPS/LTCH PPS proposed rule did include a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our final estimate.

To provide context, we note that Factor 1 is not estimated in isolation from other projections made by OACT. The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates in this final rule are generally consistent with those used for the ''2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html* under ''Downloads.'' For additional information on the development of the President's Budget, we refer readers to the OMB website at: *https://www.whitehouse.gov/omb/budget*. We recognize that our reliance on the economic assumptions and actuarial analysis used to develop the President's Budget and the Medicare Trustees Report in estimating Factor 1 has an impact on stakeholders who wish to replicate the Factor 1 calculation, such as modelling the relevant Medicare Part A portion of the budget, but we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the 2020 Medicare Trustees Report. We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2018.pdf* for a discussion of general issues regarding Medicaid projections. Additionally, as described in more detail later in this section, in the FY 2021 IPPS/LTCH PPS proposed rule, we included information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to identify Medicare DSH payments, we explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other'' and ''Discharges'' assumptions, as well as additional information regarding how we address the Medicaid and CHIP expansion.

Regarding the commenters' requests for further information on our assumptions regarding Medicaid expansion on the Medicaid population, we provide a discussion of more recent estimates and assumptions regarding Medicaid expansion as part of the discussion of the final Factor 1 for FY 2021, which also incorporates the estimated impact of the COVID–19 pandemic.

Comment: The majority of comments on Factor 1 raised concerns regarding the adverse economic effects resulting from the COVID–19 Public Health Emergency (PHE) and the impact on the estimate of Factor 1. A common concern raised by commenters was the discrepancy between the current macroeconomic conditions and the actual inputs used to estimate Factor 1 in the FY 2021 IPPS/LTCH PPS proposed rule. A commenter pointed out that the Factor 1 estimate used in the FY 2021 Final Rule would normally be generally consistent with the assumptions and projections in the Midsession Review of the President's Budget; however, the commenter noted that the Midsession Review for FY 2021 did not report updated economic assumptions and hence would not account for the impact that the COVID–

19 PHE has had and will continue to have on empirically justified DSH payments. This commenter stated that even in the absence of updated Midsession Review projections, OACT remains obligated to account for COVID–19 in projecting the amount of empirically justified Medicare DSH payments by using the latest economic forecasts from reliable sources. As in years past, this commenter, as well as many others, also emphasized the importance of the ''Other'' factor used in the calculation of Factor 1 and highlighted the impact that the increase in Medicaid enrollment associated with the adverse economic effects of the COVID–19 PHE would have on this factor. A handful of commenters also requested that CMS clarify why the ''Other'' factor, as well as the case-mix and discharge factors, have decreased as compared to previous years. A commenter believed that there would be increasing Medicaid utilization due to the pandemic and referred to the funding for COVID–19 testing and treatment for uninsured individuals made available under the Families First Coronavirus Response Act and CARES Act. This same commenter also believed staggering levels of unemployment would contribute to increased Medicaid utilization until the pandemic passes and the economy stabilizes.

Commenters highlighted the proposed decrease in Factor 1 of $919 million from FY 2020 to FY 2021 and cited several data sources that they believe would indicate that such a decrease in estimated DSH payments would be inconsistent with the current economic situation. For example, several commenters pointed out that, according to the Congressional Budget Office (CBO), the unemployment rate is projected to be 9.5 percent by the end of FY 2021, which in turn would indicate an increase in Medicaid enrollment. Many commenters also cited estimates by the Urban Institute, which estimated that 12 to 21 million people would become eligible for Medicaid as a result of losing Employer-Sponsored Insurance (ESI) due to the COVID–19 PHE. Commenters also referenced a Kaiser Family Foundation estimate that 27 million would lose ESI as of May 2, 2020, with nearly half being eligible for Medicaid. A few commenters also referenced estimates generated by independent consulting firms, one of which predicted Medicaid enrollment would increase by 30 million as a result of the adverse economic effects from the COVID–19 PHE. To this end, many stakeholders urged CMS to use more recent, or alternative data sources, to account for the projected increase in Medicaid beneficiaries in the calculation of Factor 1.

A commenter also observed that due to the COVID–19 PHE, disproportionate patient percentages (DPPs) would be expected to increase nationwide in FY 2021, increasing the projected amount of traditional DSH payments above the levels originally projected based on the economic assumptions and actuarial analysis used in the President's Budget. Finally, a handful of commenters raised the issue of deferral of inpatient non-emergency services due to the COVID–19 PHE, suggesting that these services would likely be shifted to next year, and expressing concern about the impact that this shift might have on the calculation of Factor 1 for FY 2021. Some commenters suggested that the agency take into account the shift in hospital payer mix resulting from the COVID–19 PHE, as well as hospital case volume degradation, when updating its estimates of DSH payments.

Response: We have taken into consideration the concerns commenters have raised as a result of the COVID–19 PHE in making our projection of Factor 1 for this FY 2021 IPPS/LTCH PPS final rule. We thank the commenters for their input on impact projections, such as the impact on Medicaid enrollment from the COVID–19 PHE. In updating our estimate of Factor 1, we considered, as appropriate, the same set of factors that we used in the proposed rule, as updated to account for the unique economic situation presented by the COVID–19 PHE. We note that the estimated increases in new Medicaid enrollees used for Factor 1 are generally consistent with the updated Factor 2 calculation described in the next section. The updated factors for ''Discharges'' and ''Case Mix'' incorporate the latest estimates from OACT of the impact of COVID–19 on the Medicare program. We discuss further details on the updated Factor 1 estimate and data sources in this section of the rule as part of the discussion of the final Factor 1 estimate for FY 2021.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2021. We discuss the resulting Factor 1 amount for FY 2021 in this section. For this final rule, the OACT used the most recently submitted Medicare cost report data from the March 31, 2020 update of HCRIS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2020 IPPS/LTCH PPS final rule and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The July 2020 OACT estimate for Medicare DSH payments for FY 2021, without regard to the application of section 1886(r)(1) of the Act, was approximately $15.171 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on the July 2020 estimate, the estimate of empirically justified Medicare DSH payments for FY 2021, with the application of section 1886(r)(1) of the Act, was approximately $3.793 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2021). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the OACT. Therefore, in this final rule, Factor 1 for FY 2021 is $11,378,005,107.01, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2021 ($15,170,673,476.01 minus $ 3,792,668,369.00). The Office of the Actuary's final estimates for FY 2021 began with a baseline of $14.004 billion in Medicare DSH expenditures for FY 2017. The following table shows the factors applied to update this baseline through the current estimate for FY 2021:

Factors Applied for FY 2018 through FY 2021 to Estimate Medicare DSH Expenditures Using FY 2017 Baseline						
FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2018	1.018088	0.983	1.018	1.0336	1.0530	14.747
2019	1.0185	0.966	1.009	1.02035	1.0129	14.937
2020	1.031	0.891	1.039	1.01957	0.9731	14.536
2021	1.029	1.036	0.983	0.99595	1.0437	15.171

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2018 and FY 2019 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figure for FY 2020 is based on preliminary data for 2020. The discharge figure for FY 2021 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The discharge figures for 2020 and 2021 include the estimated impact of the COVID–19 pandemic. The case-mix column shows the estimated changes in case-mix for IPPS hospitals. The case-mix figures for FY 2018 and FY 2019 are based on actual data adjusted by a completion factor. The FY 2020 increase is based on preliminary data. The FY 2021 figure is an estimate based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The case-mix factor figures for 2020 and 2021 have also been adjusted for the estimated impact of the COVID–19 pandemic. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on this information, it is assumed that 55 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2018 and 2019 resided in States that had elected to expand Medicaid eligibility, and 60 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2020 and thereafter, resided in States that had elected to expand Medicaid eligibility. In the future, these assumptions may change based on actual participation by States. The ''Other'' column also includes the estimated impacts on Medicaid enrollment from the pandemic. We note that it is estimated that Medicaid enrollment increased by 4.0 percent in FY 2020 and will increase by an additional 0.3 percent in FY 2021. For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2018.pdf*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on data from the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 81 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. We note that this is an updated assumption based on more recent data compared to the data available at the time of the proposed rule. This same assumption was used for the new Medicaid beneficiaries who enrolled in 2020 and 2021 due to the COVID–19 pandemic. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2018	2.7	-0.75	-0.6	0.4588	1.8088
2019	2.9	-0.75	-0.8	0.5	1.85
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0.0	0.5	2.9

Note: All numbers are based on the 2020 Medicare Trustees Report projections adjusted for more recent data and the estimated impact of the COVID-19 pandemic, except for the FY 2021 percentages, which are based on the most recent forecast, including the estimated impact of the COVID-19. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion of the changes in the inpatient hospital update for FY 2021.

b. Calculation of Factor 2 for FY 2021

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus a statutory adjustment of 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age.

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (a) The extent to which the source accounted for the full U.S. population; (b) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (c) the extent to which the source utilized data from the Census Bureau; (d) the timeliness of the estimates; (e) the continuity of the estimates over time; (f) the accuracy of the estimates; and (g) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32750), we proposed to use the same methodology as was used in FY 2018 through FY 2020 to determine Factor 2 for FY 2021.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we had determined that the source that, on balance, best meets all of these considerations is the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. In the FY 2021 IPPS/LTCH PPS proposed rule, we described some aspects of the methodology used to develop the NHEA that were particularly relevant in estimating the percent change in the rate of uninsurance for FY 2018 through FY 2020 that we believe continue to be relevant in developing the estimate for FY 2021. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the United States, plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. In past years, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the United States across all age groups. In addition, we

continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2018, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2018. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at: *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2018, the OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the CDC. The U.S. Census Bureau is the data collection agent for the NHIS. The NHIS results have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm*.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both CY 2020 and CY 2021. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2019 through 2028) use the latest NHEA historical data, which presently run through 2018. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

The use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

(2) Factor 2 for FY 2021

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32751), using these data sources and the previously described methodologies, the OACT estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2020 and 2021 is 9.5 percent and 9.5 percent, respectively.[433] As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified those estimates. However, for purposes of this final rule, we note that the OACT has added an addendum to the memo to reflect an updated methodology for uninsured rate projection, as discussed in our responses to comments.

As with the CBO estimates on which we based Factor 2 in prior fiscal years, the NHEA estimates are for a calendar year. In the rulemaking for FY 2014, many commenters noted that the uncompensated care payments are made for the fiscal year and not on a calendar year basis and requested that CMS normalize the CBO estimate to reflect a fiscal year basis. Specifically, commenters requested that CMS calculate a weighted average of the CBO estimate for October through December 2013 and the CBO estimate for January through September 2014 when determining Factor 2 for FY 2014. We agreed with the commenters that normalizing the estimate to cover FY 2014 rather than CY 2014 would more accurately reflect the rate of uninsurance that hospitals would experience during the FY 2014 payment year. Accordingly, we estimated the rate of uninsurance for FY 2014 by calculating a weighted average of the CBO estimates for CY 2013 and CY 2014 (78 FR 50633). We have continued this weighted average approach to rate of uninsurance projections for each Federal fiscal year since the FY 2014 IPPS/LTCH PPS final rule.

We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year more accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather

[433] Certification of Rates of Uninsured. July 31, 2020. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html*.

than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we proposed to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2021. As part of the development of the proposed Factor 2 for FY 2021, the OACT certified this estimate of the fiscal year rate of uninsurance to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. However, in the proposed rule, we noted that we might also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2021.

The calculation of the proposed Factor 2 for FY 2021 using a weighted average of the OACT's projections for CY 2020 and CY 2021 was as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2020: 9.5 percent.
- Percent of individuals without insurance for CY 2021: 9.5 percent.
- Percent of individuals without insurance for FY 2021 (0.25 times 0.095) + (0.75 times 0.095): 9.5 percent.

$1-|((0.095-0.14)/0.14)| = 1-0.3214 = 0.6786$ (67.86 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation. Therefore, we proposed that Factor 2 for FY 2021 would be 67.86 percent.

The proposed FY 2021 uncompensated care amount was \$11,518,901,035.84 * 0.6786 = \$7,816,726,242.92. (We note that this calculation is Factor 1 * Factor 2. In the proposed rule, this sentence inadvertently referenced the total amount of estimated Medicare DSH payments before the application of § 1886(r)(1), rather than 75% of that amount, as required by § 412.106(g)(1)(i). However, the proposed total uncompensated care amount was accurately included in the FY 2021 proposed rule and is shown again below).

Proposed FY 2021 Uncompensated Care Amount	\$7,816,726,242.92

We invited public comments on our methodology for calculating Factor 2 for FY 2021.

Comment: As with the comments received on proposed Factor 1, a majority of commenters discussed the proposed Factor 2 in the context of the adverse economic effects resulting for the COVID–19 PHE. Stakeholders urged OACT to update its projections of the rates of uninsurance for CY 2020 and CY 2021 to reflect changes in the rate of uninsurance due to the COVID–19 PHE, and in particular, the marked increase in the number of unemployed workers. Several commentators also pointed out that, based on the OACT projections, the uninsured rate is expected to remain fairly flat (9.5% in FY 2021 as compared to 9.4% in FY 2020); however, given the proposed decrease of \$534 million in the estimate of the amount available to make uncompensated care payments from the FY 2020 level, many commenters urged CMS to use more recent or alternative data sources to account for the increase in the rate of uninsurance due to the COVID–19 PHE. Several commenters highlighted CMS' statement in the proposed rule that it could consider more recent data that may become available for the calculation of the final Factor 2 for FY 2021.

Many commenters cited the substantial increase in the unemployment rate, and the likely loss of employer-sponsored health insurance, as the main factor influencing the uninsured rate since the outset of the COVID–19 PHE. Commenters referenced various sources for the unemployment rate, including estimates from the Bureau of Labor Statistics as well as from independent research groups. Several commenters also proposed updated estimates of the uninsured rate and alternative approaches on how to adjust Factor 2 and the estimated uncompensated care amount to reflect the impact of the COVID–19 PHE. A commenter raised the idea of using the correlation between the unemployment rate and the uninsured rate, which they projected to be 21.86%, by arguing that the uninsured rate is approximately 2.86 times the unemployment rate. Considering this relationship, the commenter estimated the uncompensated care amount for FY 2021 should be \$18 billion. The commenter further suggested that the increase in uncompensated care payments from the proposed amount could be funded by the CARES Act.

Several different estimates of the uninsured percentage were suggested by other stakeholders. Those who cited the Kaiser Family Foundation estimated that 3.8 million of the newly unemployed would remain uninsured in January 2021. A commenter stated that this would increase the number of uninsured to 35.3 million and, therefore, would increase Factor 2. Another stakeholder, also citing the Kaiser Family Foundation estimate, added that it would be unrealistic to assume that only 3.8 million people would remain uninsured in 2021 because not everyone eligible for coverage in the Affordable Care Act (ACA) exchanges or Medicaid would actually enroll in such coverage. The commenter suggested that an optimistic estimate of those actually enrolling would be closer to 75% of the newly uninsured; given this assumption, the commenter indicated that the uninsured number would actually increase by 9.6 million or 2.6 percentage points, which would increase the uncompensated care amount by 2.3 billion dollars. Several other commenters echoed this concern, stating that there is no guarantee that individuals losing ESI would actually enroll in alternative forms of coverage, primarily Medicaid and plans available through the ACA exchanges. For example, a commenter stated that previous estimates have shown that only 43% of ACA exchange eligible enroll, adding that increased Medicaid eligibility is limited to expansion states, further limiting potential enrollment.

Other commenters provided estimates developed by consulting groups of both the uninsured rate and the uncompensated care amount. For example, a commenter referenced an estimate that the total uninsured population could increase to 40 million due to the COVID–19 PHE and indicated that inputting this number into the estimate based on the National Health Expenditure Accounts (NHEA) would result in an uninsured rate of 11% to 12%. The resulting increase in Factor 2 would translate to more than one billion dollars in additional funds for uncompensated care payments. Another commenter simulated the uncompensated care amount based on the uninsured and Medicaid enrollment estimates from the Urban Institute and the Kaiser Family Foundation and found that the uncompensated care amount would be closer to \$10 billion. A handful of commenters also suggested that CMS maintain the same level of

uncompensated care funding as in FY 2020.

Several commenters urged that CMS revise its methodology for estimating Factor 2 to incorporate the effects of COVID–19 on the uninsured rate in FY 2021 and the impact of any future public health emergency.

Lastly, commenters urged CMS to be transparent in the calculation of Factor 2 and stated that agency assumptions and data sources should be accurate and publicly available.

Response: We thank the commenters for their input and their recommendations regarding the estimate of Factor 2 included in the proposed rule. Considering the unprecedented impact of the COVID–19 PHE and that more recent available data regarding levels of uninsurance have become available since the proposed rule, OACT has updated the projection of the rate of uninsurance for purposes of calculating the final Factor 2 for FY 2021. We refer readers to the addendum to the OACT memo for further details on the methodology and updated assumptions used in the calculation of the projection of the uninsurance rate. In brief, using the past estimates from NHEA from earlier this year as a baseline, OACT estimated the impacts of employment changes on insurance coverage to update the estimate of rates of uninsurance. We note that this approach takes into account more recent historical data on the rate of unemployment as published by BLS, as well as updated economic projections of those data, as published in the monthly Blue Chip Economic Indicators report, to better reflect the estimated impacts of the PHE. Regarding the commenters' suggestion for revising the Factor 2 methodology more generally to reflect the impact of public health emergencies, such as the COVID–19 PHE, we may take this recommendation into consideration for future rulemaking, as appropriate.

In response to the comments concerning transparency, we reiterate that we have been and continue to be transparent with respect to the methodology and data used to estimate Factor 2. The FY 2021 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed Factor 2 methodology as well as the data sources that would be used in making our final estimate. For purposes of this final rule, we are using an updated projected rate of uninsurance to reflect the impact of the PHE for the COVID–19 pandemic. A detailed description of the methodology used to update our estimates can be found in the accompanying memo (available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh*). Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. We continue to believe that the NHEA data and methodology that were used to estimate Factor 2 for this final rule are transparent and best meet all of our considerations for ensuring reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We further believe, given the unprecedented effects on health insurance enrollment as a result of COVID–19, that it is appropriate to update the NHEA-based projection of the FY 2021 rate of uninsurance that appeared in the proposed rule using recent relevant unemployment data from BLS, and associated projections of that metric as published in the Blue Chip Economic Indicators report, to account for these expected impacts.

After consideration of the public comments we received, we are updating the calculation of Factor 2 for FY 2021 to incorporate more recent data. The final estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS. The calculation of the final Factor 2 for FY 2021 using a weighted average of OACT's updated projections for CY 2020 and CY 2021 is as follows:

- Percentof individuals without insurance for CY 2013: 14 percent.
- Percentof individuals without insurance for CY 2020: 10.3 percent.
- Percentof individuals without insurance for CY 2021: 10.2 percent.
- Percentof individuals without insurance for FY 2021 (0.25 times 0.103) + (0.75 times 0.102): 10.2 percent.

$1-|((0.0102-0.14)/0.14)| = 1-0.2714 = 0.7286$ (72.86 percent). Therefore, the final Factor 2 for FY 2021 is 72.86 percent. The final FY 2021 uncompensated care amount is $11,378,005,107.01 * 0.7286 = $8,290,014,520.96.

c. Calculation of Factor 3 for FY 2021

(1) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year this provision was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care

costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we believed that the utilization of insured low-income patients, as measured by patient days, would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision making was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believed it was also appropriate to use proxy data to calculate Factor 3 for these years. We indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. Our analyses on balance led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses.

We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, as part of our ongoing quality control and data improvement measures for the Worksheet S–10, we referred readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCHs),'' issued on July 15, 2016 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1681OTN.pdf*). In this transmittal, as part of the process for ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that, for revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016. For the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949 through 19950), we examined hospitals' FY 2014 cost reports to see if the Worksheet S–10 data on those cost reports had changed as a result of the opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014. Specifically, we compared hospitals' FY 2014 Worksheet S–10 data as they existed in the first quarter of CY 2016 with data from the fourth quarter of CY 2016. We found that the FY 2014 Worksheet S–10 data had changed over that time period for approximately one quarter of hospitals that receive uncompensated care payments. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S–10 information was available to be used in determining uncompensated care costs contributed to our belief that we could no longer conclude that alternative data are available that are a better proxy than the Worksheet S–10 data for the costs of subsection (d) hospitals for treating individuals who are uninsured.

We also recognized commenters' concerns that, in using Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014,

the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care for FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. As a result, we would have been using older data that may provide a less accurate proxy for the level of uncompensated care being furnished by hospitals, contributing to our growing concerns regarding the continued use of low-income insured days as a proxy for uncompensated care costs in FY 2018.

To address concerns raised by commenters regarding a lack of clear and concise line level instructions, CMS issued Transmittal 10, which clarified and revised the instructions for reporting charity care on Worksheet S–10. For a discussion of the revisions and clarifications included in Transmittal 10, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42360). On September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care, as well as modifying the calculations relative to uncompensated care costs and adding edits to ensure the integrity of the data reported on Worksheet S–10. Transmittal 11 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf*. We further clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy (hereinafter referred to as Financial Assistance Policy or FAP) may be included on Line 20, Column 1 of Worksheet S–10. These clarifications applied to cost reporting periods beginning on or after October 1, 2013. We also modified the application of the CCR. We specified that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs. As discussed in more detail in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42360 and 42361), we have also provided opportunities for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), due to the overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we expected to begin audits of the Worksheet S–10 in the Fall of 2018. The audit protocol instructions were still under development at the time of the FY 2019 IPPS/LTCH PPS final rule; yet, we noted the audit protocols would be provided to the MACs in advance of the audit. Once the audit protocol instructions were complete, we began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule. The audits began with 1 year of data (that is, FY 2015 cost reports) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness. We chose to begin the audits with the FY 2015 cost reports primarily because this was the most recent year of data that we had broadly allowed to be resubmitted by hospitals, and many hospitals had already made considerable efforts to amend their FY 2015 reports in preparation for the FY 2019 rulemaking. We also considered that we had used the FY 2015 data as part of the calculation of the FY 2019 uncompensated care payments; therefore, the data had been subject to public comment and scrutiny.

(2) Background on the Methodology Used To Calculate Factor 3 for FY 2020

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19418 and 19419), we proposed to use audited FY 2015 data to calculate Factor 3 for FY 2020. Given that we had conducted audits of the FY 2015 Worksheet S–10 data and had previously used the FY 2015 data to determine uncompensated care payments, and the fact that the FY 2015 data were the most recent data that we had allowed to be resubmitted to date, we believed, on balance, that the FY 2015 Worksheet S–10 data were the best available data to use for calculating Factor 3 for FY 2020.

In the FY 2020 IPPS/LTCH PPS proposed rule, we recognized that, for FY 2019, we used 3 years of data in the calculation of Factor 3 in order to smooth over anomalies between cost reporting periods and to mitigate undue fluctuations in the amount of uncompensated care payments from year to year. However, we stated that, for FY 2020, we believed mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result, which would be counter to our original goal in using 3 years of data. As we stated in the FY 2020 IPPS/LTCH PPS proposed rule, to the extent that the audited FY 2015 data for a hospital are relatively different from its unaudited FY 2014 data and/or its unaudited FY 2016 data, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we continued to use 3 years of data to calculate Factor 3. As an example, we noted that approximately 10 percent of

audited hospitals had more than a $20 million difference between their audited FY 2015 data and their unaudited FY 2016 data.

Although we proposed to use the Worksheet S–10 data from the FY 2015 cost reports to calculate Factor 3 for FY 2020, we acknowledged that some hospitals had raised concerns regarding some of the adjustments made to the FY 2015 cost reports following the audits of those cost reports (for example adjustments made to Line 22 of Worksheet S–10). In particular, hospitals had raised concerns regarding the instructions in effect for FY 2015, especially compared to the reporting instructions that were effective for cost reporting periods beginning on or after October 1, 2016, contending that some adjustments would not have been made if CMS had chosen as an alternative to audit the FY 2017 reports. Accordingly, we sought public comments on whether the changes in the reporting instructions between the FY 2015 cost reports and the FY 2017 cost reports had resulted in a better common understanding among hospitals of how to report uncompensated care costs and improved relative consistency and accuracy across hospitals in reporting these costs. We also sought public comments on whether, due to the changes in the reporting instructions, we should use a single year of uncompensated care cost data from the FY 2017 reports, instead of the FY 2015 reports, to calculate Factor 3 for FY 2020.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use the FY 2015 Worksheet S–10 cost report data in the methodology for determining Factor 3 for FY 2020. Although some commenters expressed support for the alternative policy of using the FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules, emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. We also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

With respect to the Worksheet S–10 data, we indicated our belief that the definition of uncompensated care adopted in FY 2018 was still appropriate because it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, including charity care costs and non-Medicare bad debt costs. Therefore, for purposes of calculating Factor 3 and uncompensated care costs for FY 2020, we again defined ''uncompensated care'' as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

In the FY 2020 IPPS/LTCH PPS final rule, we continued to apply the following policies as part of the Factor 3 methodology: (1) The merger policies that were initially adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020); (2) the policy for providers with multiple cost reports, beginning in the same fiscal year, of using the longest cost report and annualizing Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy for the rare cases where a provider has multiple cost reports, beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year, such that the hospital has no cost report for that fiscal year, of using the cost report that spans both fiscal years for the latter fiscal year; and (4) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 19419), we finalized a modified new hospital policy for new hospitals that did not have data for the cost reporting period(s) used in the Factor 3 calculation for FY 2020. Generally, new hospitals do not yet have available data to project their eligibility for DSH payments because there is a lag until the SSI ratio and Medicaid ratio become available. However, we noted that there are some hospitals (that is, hospitals with CCNs established after October 1, 2015) that have a preliminary projection of being eligible for DSH payments based on their most recent available disproportionate patient percentages. Under the modified policy adopted for FY 2020, new hospitals that are eligible for Medicare DSH may receive interim empirically justified DSH payments. However, because these hospitals do not have a FY 2015 cost report to use in the Factor 3 calculation and the projection of eligibility for DSH payments is still preliminary, the MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2020 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2020, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2020 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2015 cost reports for all DSH-eligible hospitals. In the FY 2020 IPPS/LTCH PPS final rule, we noted that, given the time period of the data used to calculate Factor 3, any hospitals with a CCN established after October 1, 2015, would be considered new and subject to this policy in FY 2020.

For a discussion of the policy that we finalized for FY 2020 for new Puerto Rico hospitals, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370 and 42371). In brief, Puerto Rico hospitals that do not have a FY 2013 cost report are considered new hospitals and subject to the new hospital policy, as previously discussed. Specifically, the numerator of the Factor 3 calculation will be the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2020 cost report and the denominator is the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals. We stated that we believed the discussion in the FY 2020 IPPS/LTCH PPS proposed rule of our intent to determine Factor 3 for these hospitals using their uncompensated care costs gave new Puerto Rico hospitals sufficient time to take the steps necessary to ensure that their uncompensated care costs for FY 2020 are accurately reported on their FY 2020 Worksheet S–10. In addition, we indicated that we expect MACs to review FY 2020 reports from new hospitals, as necessary, which will address past commenters' concerns regarding the need for further review of Puerto Rico hospitals' uncompensated care data before these data are used to determine Factor 3.

In the FY 2020 IPPS/LTCH PPS final rule (83 FR 42371), for Indian Health Service and Tribal hospitals, and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report, we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), the use of data from

Worksheet S–10 to calculate the uncompensated care amount for Indian Health Service and Tribal hospitals may jeopardize these hospitals' uncompensated care payments due to their unique funding structure. With respect to Puerto Rico hospitals that would not be subject to the new hospital policy, we indicated that we continued to agree with concerns raised by commenters that the uncompensated care data reported by these hospitals need to be further examined before the data are used to determine Factor 3. Accordingly, for these hospitals, we determined Factor 3 based on Medicaid days from FY 2013 and the most recent update of SSI days. The aggregated amount of uncompensated care that is used in the Factor 3 denominator for these hospitals continued to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH-eligible hospitals using the low-income insured days proxy. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2020, we computed Factor 3 for each hospital by—

Step 1: Selecting the provider's longest cost report from its Federal fiscal year (FFY) 2015 cost reports. (Alternatively, in the rare case when the provider has no FFY 2015 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2015 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualizing the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combining annualized uncompensated care costs for hospitals that merged.

Step 4: Calculating Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a FY 2013 cost report using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). (Alternatively, in the rare case when the provider has no FFY applicable cost report because the cost report for the previous Federal fiscal year spanned the time period, the previous Federal fiscal year cost report would be used in this step.) The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals. Consistent with the policy adopted in the FY 2019 IPPS/LTCH PPS final rule, if a hospital did not have both Medicaid days for FY 2013 and SSI days for FY 2017 available for use in the calculation of Factor 3 in Step 4, we considered the hospital not to have data available for Step 4.

Step 5: Calculating Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2015 cost report data (from Step 3). The hospitals for which Factor 3 was calculated in Step 4 were excluded from this calculation.

We amended the regulations at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*6*) to reflect the methodology for computing Factor 3 for FY 2020.

(3) Methodology for Calculating Factor 3 for FY 2021 and Subsequent Fiscal Years

(a) Use of Audited FY 2017 Data To Calculate Factor 3 for FY 2021

Since the publication of the FY 2020 IPPS/LTCH PPS final rule, we have continued to monitor the reporting of Worksheet S–10 data in order to determine the most appropriate data to use in the calculation of Factor 3 for FY 2021. Audits of FY 2017 cost reports began in June 2019 and those audited reports were available in time for the development of the proposed rule. Feedback from the audits of the FY 2015 reports and lessons learned were incorporated into the audit process for the FY 2017 reports. We again chose to audit 1 year of data (that is, FY 2017) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness.

Given that the FY 2017 Worksheet S–10 data were submitted under the revised cost reporting instructions that were effective on October 1, 2017, and we have also undertaken provider outreach regarding potentially aberrant data in FY 2017 reports and conducted audits of these data (84 FR 42371), in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32755), we stated that we believe, on balance, that the FY 2017 Worksheet S–10 data are the best available data to use for calculating Factor 3 for FY 2021. For a detailed discussion of the cost reporting instruction changes between the FY 2015 and FY 2017 reports, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368 and 42369). For the reasons discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules (84 FR 19419 and 84 FR 42364), we continue to believe that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. To the extent that the audited FY 2017 data for a hospital are relatively different from its FY 2015 data (whether audited or unaudited) and/or its unaudited FY 2016 data, we potentially would be diluting the effect of the revisions to the cost reporting instructions and our considerable auditing efforts, while introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3 for FY 2021. As explained in the FY 2021 IPPS/LTCH proposed rule, we recognize that the FY 2015 reports include audited data for some hospitals, however, the FY 2017 cost reports are the most recent year of audited data and, as previously discussed, reflect the revisions to the Worksheet S–10 cost report instructions that were effective on October 1, 2017.

Accordingly, we proposed to use a single year of Worksheet S–10 data from FY 2017 cost reports to calculate Factor 3 in the FY 2021 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. As discussed in a later section, we proposed to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for one more year. We noted that the uncompensated care payments to hospitals whose FY 2017 Worksheet S–10 data had been audited represented approximately 65 percent of the total uncompensated care payments for FY 2021. For purposes of the FY 2021 proposed rule, we used a HCRIS extract updated through February 19, 2020. We noted that we intended to use the March 2020 update of HCRIS for the FY 2021 final rule and the respective March updates for all future final rules. However, we invited the public to submit comments on this intention regarding the use of the March update of HCRIS, and indicated that we might also consider the use of more recent data that may become available

after March 2020, but prior to the development of the final rule, if appropriate, for purposes of calculating the final Factor 3 for purposes of the FY 2021 IPPS/LTCH PPS final rule.

Comment: Several commenters expressed concern about the redistribution of uncompensated care payments in the context of CMS not using the most recent and accurate HCRIS data. To this end, several commenters urged CMS to use the latest HCRIS extract available for the calculation of Factor 3. Among these commenters, the majority preferred the use of a June 30 HCRIS extract, pointing out that CMS has used a June quarterly extract in both the FY 2018 and FY 2019 IPPS/LTCH PPS final rules. Commenters reasoned that using a later HCRIS extract would allow providers more flexibility to amend materials that may have been overlooked in the proposed rule, and according to commenters, this is especially important due to the effect of the COVID–19 PHE. A commenter suggested CMS use a HCRIS extract as close as possible to the close of the comment period for the FY 2021 rulemaking cycle. Another commenter suggested the agency use the February or March HCRIS data extract for future proposed rules and the June HCRIS extract for FY 2021 and future final rules, mentioning that this would allow for more time to complete the audits, to contest results, and to handle unforeseen circumstances or delays. Additionally, a commenter expressed concern that if CMS did not use the June 30 HCRIS extract in the FY 2021 final rule, then their most recent CCR would not be accounted for, placing their hospital above the proposed CCR trim ceiling.

Response: We thank commenters for sharing their concerns regarding the HCRIS extract used in the FY 2021 IPPS/LTCH final rule. We agree with commenters that recommended using the June 2020 HCRIS data for calculating Factor 3 for FY 2021, due to this year's public health emergency, which, for some hospitals, delayed the filing of amended cost report information and/or correction of report version discrepancies in time for the March HCRIS extract; therefore we are finalizing the use of the June 30 HCRIS extract to calculate Factor 3 for this FY 2021 IPPS/LTCH PPS final rule. We believe on balance this is the best available data for purposes of calculating Factor 3 for FY 2021. In the rare situations where a MAC mishandled a report in the upload process, such as by accepting an amended report, reopening a report, and/or adjusting uncompensated care cost data on a report before the June 30 cut off, but the corrected uncompensated care cost data were inadvertently omitted from the June 30, 2020 extract of the HCRIS, we used the corrected version of the report after confirming the appropriate report version with the applicable MAC.

Regarding commenters' suggestions that we use the February or March HCRIS for all future proposed rules, we note that at this time, we intend to use the most recent data available for the applicable rulemaking, which generally means the respective December HCRIS extract for purposes of Factor 3 calculations in future proposed rules. We expect that the December HCRIS extract would reflect the completed Worksheet S–10 audit results available in time for development of the respective proposed rules and the respective HCRIS extract public use files, which are posted on the CMS website quarterly, would also include the most recent audited cost report information for the applicable fiscal year, and be available for public scrutiny. Furthermore, as noted in the FY 2021 IPPS/LTCH PPS proposed rule, we continue to intend to use the respective March HCRIS for future final rules. We expect the COVID–19 PHE will not have the same impact on future rulemaking as it did for the FY 2021 rulemaking. However, we may revisit this topic of the appropriate HCRIS extract, if necessary, in future rulemaking.

Comment: A large majority of comments expressed general support for the use of Worksheet S–10 to estimate each hospital's share of uncompensated care costs in FY 2021, FY 2022, and/or in future years. Some commenters argued that audited Worksheet S–10 data are more accurate as compared to the proxy method previously used, and others commended CMS for its efforts to improve the data through revised instructions and audits. A few commenters expressed opposition to using Worksheet S–10 data and recommended that CMS reconsider using it for the calculation of uncompensated care costs, especially in the absence of auditing all DSH-eligible hospitals. A commenter expressed concern about the accuracy of Worksheet S–10 data and noted that even with the audits, hospitals are reporting charity care and defining write-offs inconsistently and suggested CMS consider alternative methods to the Worksheet S–10 in consultation with hospitals.

Another commenter asserted that using Worksheet S–10 data to calculate Factor 3 could result in an inequitable distribution because Worksheet S–10 does not ''offset hospital UC [uncompensated care] losses with non-Medicare sources of subsidies such as Medicaid DSH and related Medicaid waiver [uncompensated care] pool funds.'' Other commenters requested additional standardization in the reporting of uncompensated care. A commenter expressed concern that the data reported by hospitals may not be comparable across all hospitals noting, for example, a difference of opinion among hospitals about characterizing ''denied claims as charity care if the hospital's financial assistance policy says the patient is not responsible for payment, even though that is a contractual or government payment requirement.'' Another commenter noted a case where discounts for uninsured and underinsured patients required by state mandates were disallowed by a MAC because such mandates were not covered by their charity care policy.

Response: We appreciate the support for our proposal to use Worksheet S–10 data for the computation of Factor 3. We also appreciate the input from those commenters who are opposed to the use of data from Worksheet S–10 in the calculation of Factor 3. Regarding those comments which note that the Worksheet S–10 data are not accurate, and that the use of the Worksheet S–10 data should be reconsidered on that basis, we note that as described in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to continue to use Worksheet S–10 cost report data in FY 2021 based upon the results of analyses of Worksheet S–10 data, conducted both internally and by stakeholders, which demonstrate that Worksheet S–10 accuracy has improved over time. As part of our ongoing quality control and data improvement measures, we have revised the cost report instructions (Transmittal 11). We have conducted audits of the FY 2017 Worksheet S–10 data, and have now begun auditing the FY 2018 Worksheet S–10 data for an expanded number of hospitals to further improve provider reporting and overall accuracy. Moreover, as hospitals gain more experience with completing the Worksheet S–10 and build upon lessons learned from the audits, we believe the data obtained from these cost reports will continue to improve and become more consistent. Therefore, we have concluded that the Worksheet S–10 data is the best available source for the uncompensated care costs of subsection (d) hospitals.

Comment: Many commenters supported the use of a single year of FY 2017 Worksheet S–10 data for the

calculation of Factor 3 for FY 2021. Commenters noted that the FY 2017 cost reports are the most recent reports which have been subject to audit and that these audits have continued to improve the accuracy and reliability of Worksheet S–10 data over time. Supporters of this proposal also argued that FY 2017 Worksheet S–10 data have been audited and stated that audited hospitals are expected to receive 65 percent of the proposed total uncompensated care payments for FY 2021. A handful of commenters also pointed out that it would be inappropriate to blend audited data with unaudited data, which could lead to inaccurate and non-representative uncompensated care payments for some hospitals if the unaudited cost reports contained reporting errors. In addition, several commenters indicated that the FY 2017 cost reports reflect the first year of reported data under the most recent revised Worksheet S–10 instructions, which were effective for cost reporting periods beginning on or after October 1, 2016.

Many commenters expressed opposition to using a single year of Worksheet S–10 data for the calculation of FY 2021 uncompensated care payments and for future years. The primary concern expressed by these stakeholders was the possibility that such an approach would lead to significant variation in year-to-year payments, especially in light of outside factors that may affect a hospital's finances. These commenters pointed to CMS's historical practice of using data from multiple years to determine uncompensated care payments and argued that such an approach would mitigate year-to-year fluctuations and avoid a skewed distribution of uncompensated care payments. To this end, a commenter noted that some hospitals reported extreme changes in uncompensated care costs from FY 2017 to FY 2018 and according to the commenter, in one example, the change was over 500 percent. The commenter added that less than one-third of hospitals reported changes in uncompensated care that were less than ten percent.

The most common alternative proposal among commenters who opposed the use of a single year of FY 2017 data for the calculation of Factor 3 in FY 2021 was the use of three years of historical Worksheet S–10 data. A commenter specifically suggested the use of FY 2015, FY 2016, and FY 2017 Worksheet S–10 data. Another commenter recommended that CMS use FY 2014, FY 2015, and FY 2016 data as a transition policy. Other commenters recommended a blend of FY 2015 and FY 2017 data since both years were subject to audits. Similar to this alternative, another commenter proposed that for the allocation of FY 2021 uncompensated care payments, CMS use a 50/50 blend, derived from the FY 2020 Factor 3 and a Factor 3 calculated using FY 2017 Worksheet S–10 data. There was also a commenter that requested that we maintain total national uncompensated care payments at the same level as in FY 2020.

Some stakeholders offered suggestions regarding the uncompensated care payment calculation that appear outside of the scope of the proposed methodology. Such recommendations included that CMS change the distribution of uncompensated care payments so that the allocation is based not on only uncompensated care costs but also on the disproportionate share percentage (DPP); set a cap on per discharge uncompensated care payments not to exceed 100 percent of DRG amounts; establish a transition period for hospitals facing a significant (5 percent) decrease in uncompensated care payments for a given year; and reevaluate the uncompensated care payment formula to achieve parity between rural and urban payments. In addition, some commenters requested that we consider adjusting uncompensated care costs in this FY 2021 rulemaking to reflect the impact of the COVID–19 PHE, rather than waiting until FY 2024 or FY 2025 when the current year's data (FY 2020) may be used for uncompensated care payment calculations. In relation to this recommendation, a commenter noted that, while the effect of the COVID–19 PHE would vary based upon geographic areas, they would expect a redistributional impact on future uncompensated care payments, and suggested that CMS begin to consider ways to dampen potential downward fluctuations in uncompensated care costs at the hospital level.

Response: We are grateful to those commenters who expressed their support for our proposed policy of using the FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2021. As noted in the FY 2021 IPPS/LTCH PPS proposed rule, we believe, that, on balance, mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. To the extent that the audited FY 2017 data for a hospital are relatively different from its unaudited FY 2016 and/or (audited or unaudited) FY 2015 data, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3.

We also note that if, for example, a blend of FY 2015, FY 2016, and/or FY 2017 cost report data were to be used, some hospitals in states that expanded Medicaid eligibility during this time period may have experienced significant reductions in uncompensated care costs following the expansion due to increased Medicaid coverage covering many previously uninsured individuals. In this situation, if an average that included pre-expansion uncompensated care cost data were used, the Factor 3 calculated for the hospital may be a less accurate reflection of the relative uncompensated care burden of the hospital. Thus, we believe using only the FY 2017 cost report data will result in a more accurate and more updated reflection of each hospital's proportion of uncompensated care costs. We also agree with those commenters that noted FY 2017 cost reports reflect the first year of data reported under the revised to Worksheet S–10 instructions through Transmittal 11, which further improved the data quality. Accordingly, we are finalizing without modification our proposal to use FY 2017 cost report data, which we believe is the best available data, to calculate Factor 3 for FY 2021.

For the same reasons, we also continue to have confidence that the best available data in future years will be the Worksheet S–10 data for cost reporting years for which audits have been conducted. In addition, we continue to believe that establishing a policy that would apply not only for FY 2021, but also for all subsequent fiscal years would provide greater predictability regarding the basis for determining future uncompensated care payments.

Regarding the commenters' suggestion to adjust uncompensated care costs in this rulemaking to reflect the impact of the COVID–19 PHE, even if such a policy change were appropriate for FY 2021 it is not clear what the methodology would be for determining such an adjustment and what data source could be used. Because the cost reporting data from the COVID–19 PHE time period is not yet available to be analyzed, we believe it would be premature to attempt in this rulemaking to modify the methodology for determining uncompensated care payments for a future year specifically to address the impact of the COVID–19 PHE. We will consider this issue further in future rulemaking, if appropriate.

Regarding commenters' concerns and suggestions that were outside of the scope of the proposed rule's methodology, separate from the cost report years from historical Worksheet S–10 data, we appreciate commenters' input and note that we may consider these and other considerations in future rulemaking.

The following comments relate to the Worksheet S–10 audit process:

Comment: As in previous years, the auditing process for the FY 2017 Worksheet S–10 was a common topic among many commenters. Several commenters agreed that the data from audited FY 2017 Worksheet S–10s have improved in accuracy when compared to previous years of data, including the data used to calculate Factor 3 under the proxy methodology in previous years. Other commenters also commended CMS's efforts to improve the Worksheet S–10 data through the audit process and revised instructions.

Still, many commenters expressed concerns with the Worksheet S–10 audits. Some commenters recommended that CMS implement a comprehensive audit process, similar to the audit process used for the wage index noting that Worksheet S–10 audits should include the same level of scrutiny. Many commenters requested that CMS establish a standardized, streamlined process across auditors, which would include uniform templates for cost report submissions, acceptable documentation regarding audit requirements, and consistent timelines for information submissions. A commenter noted that their hospitals faced significant reporting burden providing auditors with the necessary audit documentation and communicating between MAC auditors, which delayed their Worksheet S–10 audits.

Stakeholders also urged CMS to conduct consistent and equitable audits across providers. Others suggested that CMS set a clear timeframe for communication and revisit the scope of the audits to target specific data elements, which would decrease provider burden. Related to this, another commenter requested that CMS work with the MACs to streamline the audit process and avoid situations where hospitals would have to resubmit data in a different template, which would only add administrative burden on hospitals.

To this end, a commenter proposed that CMS clarify that MACs can only request documentation referenced in hospitals' Financial Assistance Policies (FAP), as well as confirm that the purpose of the Worksheet S–10 audits is to check if hospitals are following their FAP. Additionally, commenters advised CMS to minimize the administrative burden of excessive reporting requirements imposed by the MACs, such as requests for overly detailed information like patients' social security numbers and birth dates, and the solicitation of information not yet generally available in hospitals' financial recordkeeping systems.

Additionally, several commenters suggested that CMS ensure transparency in the audit process by making the audit materials and protocols publicly available. They also urged CMS to develop a transparent timeframe for the audit process, with adequate lead time and communication to providers about expectations. Commenters also requested that CMS disclose the criteria used to identify hospitals subject to audits, and prepare communications regarding expectations for the audit and any audit guidance before the rulemaking cycle. A commenter noted that CMS's ''policy of opacity'' only results in inconsistent interpretations of audit guidance by the MACs. Other commenters made recommendations regarding the timeliness of the audits, such as following a set annual timeframe similar to the approach used in the wage index audits.

Commenters also expressed discontent regarding the limited time allowed for providers to respond to adverse adjustments, resolve differences, and submit supporting documentation. These commenters urged CMS to begin the audits in a timely manner to avoid situations with short response times. Regarding the audit timeline, a commenter proposed that CMS begin the audit process on an annual basis in February or March, with the end date remaining December 31 of the applicable year. According to this commenter, the proposed timeline would provide MACs sufficient time to work with providers and to schedule Worksheet S–10 audits.

Additionally, commenters urged CMS to consider working with MACs in developing the Worksheet S–10 audit process to further promote clarity and consistency. To this end, a commenter requested that in developing Worksheet S–10 audit protocols, CMS consider using one MAC either to do all of the audits or to develop the audit rules to be employed by all MACs. A different commenter noted that there are hospital systems subject to audits conducted by multiple MACs, and these providers have observed inconsistent audit adjustments to uncompensated care amounts. This commenter noted that these inconsistencies are indicative of MACs not interpreting and following CMS's audit instructions in a standardized way.

Commenters noted the need for a timely review and timely appeals process for any Worksheet S–10 errors or inconsistent audit disallowances. As part of raising their concern regarding the lack of an appeals process for Worksheet S–10 audits, a commenter proposed that disallowed uncompensated care costs be appealed to the Provider Reimbursement Review Board (PRRB), which the commenter asserted would be consistent with the process used to appeal other items from the Medicare cost report. Another commenter asserted that there would not be sufficient time to appeal audit disallowances or adjustments under a normal PRRB process before the data are used by CMS. Some commenters recommended that CMS establish an expedited process for appeal to an appropriate oversight body, which would allow hospitals to obtain reversals of errors by MACs and address any inconsistencies and/or improper disallowances. A commenter suggested the use of an abbreviated appeals process, similar to the process used in the wage index development process.

Commenters also provided additional recommendations for future audits specifically to improve data consistency. They suggested that CMS audit all hospitals and utilize a single auditor, or at least establish and enforce a formal and uniform audit process. Several commenters recommended using a similar approach to the desk review process conducted for the purposes of the wage index. Many commenters expressed concerns that not all providers have had their Worksheet S–10 data audited. For example, a commenter noted that while some hospitals have been audited more than once, other DSH hospitals have not been audited at all. Some commenters urged CMS to complete audits for the remaining hospitals that did not have the Worksheet S–10 from their FY 2017 cost report audited before the FY 2021 rulemaking and others strongly felt that CMS should audit all DSH-eligible hospitals on an ongoing basis. A commenter stated that if CMS cannot audit 100 percent of hospitals, the agency should focus on the biggest recipients of DSH payments.

A commenter requested clarification of whether Sole Community Hospitals (SCHs) that are paid under their hospital-specific rates are subject to the Worksheet S–10 audits. Similarly, a few commenters suggested that SCHs should be excluded from the Worksheet S–10 audits to improve efficiency and reduce

burden, as they are not eligible for DSH payments and their data are not included in the totals used for allocation of uncompensated care payments. A commenter asserted that there is a lack of justification for a requirement to audit data that is of no use for Medicare payment purposes. A commenter suggested that non-DSH eligible SCHs zero out uncompensated care on the Worksheet S–10, but also recognized that this approach may not be beneficial as it would appear as if the hospitals are not providing any uncompensated care.

Finally, a few commenters suggested new approaches to auditing and/or reviewing Worksheet S–10 data. A commenter recommended that CMS establish a program of periodic timely data review for the identification of discrepancies and troublesome data. This commenter also proposed that CMS start the process of reviewing FY 2019 cost data as it is reported, and that CMS to engage in FY 2018 data audits during FY 2021 for hospitals that are projected to receive DSH payments, but have not yet been audited. Another commenter recommended that in order to utilize resources more efficiently, CMS could work with the Internal Revenue Service (IRS) as it also audits hospital uncompensated care costs reported on the Form 990 and both agencies have similarly aligned goals. They also suggested that CMS continue Worksheet S–10 audits, but explore ways in which it can more efficiently utilize audit resources, such as, by relying on hospitals' audited financial statements. In addition, this commenter requested that CMS apply the same audit criteria that are used for retrospective audits of empirically justified DSH payments, which use SSI/Medicare and Medicaid eligible days/indigent care days. The commenter also stated that hospitals should have the same protections afforded by the appeal rights for empirically justified DSH payments.

Response: We thank commenters for their feedback on the audits of the FY 2017 Worksheet S–10 data and their recommendations for future audits. As we have stated previously in response to comments regarding audit protocols, these are provided to the MACs in advance of the audit so as to assure consistency and timeliness in the audit process. We began auditing the FY 2017 Worksheet S–10 data for selected hospitals last year so that the audited uncompensated care data for these hospitals would be available in time for use in the FY 2021 IPPS/LTCH PPS proposed rule. We chose to focus the audit on the FY 2017 cost reports in order to maximize the available audit resources. We note that FY 2017 is the first year of data under the revised cost report instructions included in Transmittal 11. In response to the consistent feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we have also started the process of auditing FY 2018 Worksheet S–10 data.

Regarding commenters' recommendations to establish an audit and appeals process for the Worksheet S–10 similar to the process used for the wage index audits, at this point we do not plan on introducing such a process in order to maximize limited audit resources. Attempting to replicate the wage index audit process would exceed our current audit resources and require shifting resources from other audit work, for example potentially negatively impacting the wage index audit itself in the attempt to replicate it. The wage index impacts a far greater proportion of national hospital payments than the proportion impacted by Medicare uncompensated care payments. We appreciate all commenters' input and recommendations on how to improve our audit process and reiterate our commitment to work with the MACs and providers on audit improvements, including changes to increase the efficiency of the audit process, building on the lessons learned in previous audit years.

We also appreciate the different suggestions for a potential audit timeline. We thank the commenters for their suggestions, but at this time, we do not intend to establish fixed start date for audits across MACs so that we can retain the flexibility to use our limited audit resources to address and prioritize audit needs across all CMS programs each year. We note that MACs work closely with providers regarding scheduling dates during the Worksheet S–10 audit process.

Regarding commenters' requests to make public the audit instructions and criteria, as we previously stated in the FY 2020 IPPS/LTCH final rule (84 FR 42368) and prior rules, we do not make review protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only. Additionally, we recognize that a number of commenters suggested we audit all hospitals. We note that limited resources do not allow us to audit all providers. However, as discussed in the FY 2021 IPPS LTCH PPS proposed rule (85 FR 32756), the proposed uncompensated care payments to hospitals whose FY 2017 Worksheet S–10 data have been audited represented approximately 65 percent of the proposed total uncompensated care payments for FY 2021, which is an increase from the FY 2015 audits. Also, we are in the process of auditing FY 2018 Worksheet S–10 data and expect that the number of audits conducted will continue to increase over time, resulting in improved Worksheet S–10 data over the years as more cost report years are audited.

Concerning the suggestions to exclude Sole Community Hospitals (SCHs) from audits of Worksheet S–10 when the hospitals are paid under their hospital-specific rate, we note that all hospitals are required to maintain documentation for cost reporting, including Worksheet S–10. We also note that there may be some uncertainty whether a hospital will ultimately be paid based on its hospital specific rate, since that review occurs during settlement process through the cost report. For example, there may be timing considerations with projecting which SCHs will be paid under the IPPS Federal rate, in addition SCH status may change over time.

Regarding the recommendation that we review FY 2019 data as they are reported, we note that time and audit resources are limited, and as discussed previously, we are currently in the process of reviewing FY 2018 Worksheet S–10 data, which is the most recent year of broadly available cost report data. With respect to the comment recommending that we work with the IRS to utilize audit resources more efficiently, we note that the instructions for the IRS' Form 990 are not the same as for the Worksheet S–10. In addition, we note that the requirement to report on the IRS Form 990 is limited to non-profit hospitals.

Concerning the request to apply the same audit criteria that are used for empirically justified DSH payments, those audit protocols are also confidential and are for CMS and MAC use only, and we continue to believe that audit protocols (*e.g.* critieria) should be confidential, so we disagree with commenter to make public any audit protocols. To the extent that the commenter is implying that the confidentiality of the audit protocols causes inconsistency in auditing across the MACs, we also disagree and will continue to work with the MACs each year to ensure a consistent audit process across providers and MACs.

As noted in earlier discussion, after consideration of the comments received we are finalizing without modification our proposal to use Worksheet S–10 data from FY 2017 cost reports to calculate Factor 3 for FY 2021 for all hospitals, with the exception of IHS and

Tribal hospitals and Puerto Rico hospitals.

(b) Use of the Most Recent Available Single Year of Audited Worksheet S–10 Data To Calculate Factor 3 for All Subsequent Fiscal Years

While the number of audited hospitals may change from year to year depending on audit experience and the availability of audit resources, we expect the Worksheet S–10 data for an increasing number of hospitals will be audited in future cost reporting years. As a result, we have confidence that the best available data in future years will be the Worksheet S–10 data for cost reporting years for which audits have been conducted. In addition, we believe that establishing a policy that would apply not only for FY 2021, but also for all subsequent fiscal years would help providers have greater predictability for planning purposes. Therefore, we proposed that for FY 2022 and all subsequent fiscal years, we would use the most recent single year of cost report data that have been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments to calculate Factor 3 for all eligible hospitals, with the exception of Indian Health Service and Tribal hospitals. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32756), we noted that we intended to consider the comments received on this proposal for FY 2022 and subsequent fiscal years, and might revisit it either in the final rule or through future rulemaking.

Comments: A few commenters supported the use of a single year of audited Worksheet S–10 data for FY 2022 and subsequent years. In contrast, while the majority of commenters supported the use of one year of FY 2017 Worksheet S–10 data for FY 2021 uncompensated care payments, most commenters argued for a transitional period where ultimately multiple years of audited Worksheet S–10 data would be used to determine Factor 3 for future years, especially when sufficient years of audited data reported under the revised reporting instructions are available. According to these commenters, such an approach would mitigate year-to-year fluctuations in uncompensated care payments. A commenter stated that it is impossible to foresee what potential shortcomings in the data or concerns with the audit process could arise. Many commenters urged CMS not to finalize the policy of using the most recent year of audited Worksheet S–10 data beyond FY 2021. These commenters believed that finalizing the proposal would prevent opportunities to assess and comment on peculiarities in the data to be used in determining Factor 3 for future years.

Consistent with these recommendations, a commenter proposed that for FY 2022 equally weighted blocks of audited FY 2017, FY 2018, and ''preliminarily-reviewed'' FY 2019 Worksheet S–10 data be used to determine Factor 3 with a rolling three-year average applied moving forward. There was also a handful of commenters that requested a three-year average as a phased approach. For example, a commenter suggested that FY 2017 and FY 2018 Worksheet S–10 data be used for the FY 2022 payments and then a rolling three-year average beginning with FY 2023. Additionally, commenters recommended that CMS monitor payments over time to assure data anomalies are addressed. To this end, a commenter urged CMS to allow for monitoring and review of uncompensated care payment volatility and audits of all hospitals' Worksheet S–10 data, before implementing the use of a single year of Worksheet S–10 data for FY 2022 and subsequent years.

Some commenters acknowledged the efforts CMS has taken to improve the accuracy of Worksheet S–10 data through the FY 2015 and FY 2017 audit process. A commenter provided an analysis that indicated the audits have improved the reliability and accuracy of Worksheet S–10 data. Another commenter indicated their support for the processes implemented by CMS and the MACs to ensure the integrity of Worksheet S–10 data.

Still, several commenters expressed concerns about the accuracy of Worksheet S–10 data. Some commenters recommended CMS implement a fatal cost report edit on Worksheet S–10 to guarantee completeness and consistency in reporting. Another commenter requested that CMS provide a 14-day period for hospitals to submit corrections arising from the mishandling of data by MAC and/or CMS. While this commenter recognized that these situations are uncommon, they urged that a 14-day time period would be sufficient to improve the uncompensated care cost allocation and would be consistent with the 15-day period we proposed to allow for review and correction of merger listings following the publication of this final rule.

Response: We thank commenters for their continued concern regarding the accuracy of Worksheet S–10 data and for their constructive feedback. As noted by some commenters, our continued efforts have improved the accuracy for Worksheet S–10 data. We believe that continued use of Worksheet S–10 for the calculation of Factor 3 along with the revisions made to the instructions through Transmittal 10 (November 2016) and Transmittal 11 (September 2017), as well as the FY 2015 and FY 2017 audits, will improve the accuracy, consistency, and quality of the reported data.

We believe using the most recent audited data available before the applicable Federal fiscal year will more accurately reflect a hospital's uncompensated care costs, as opposed to averaging multiple years of data. Consistent with the discussion in the previous section, if a hospital has relatively different data between cost report years, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3. Therefore, we believe using a single year of audited cost report data is an appropriate methodology for FY 2022 and subsequent years.

Concerning the suggestion that implement a fatal edit on Worksheet S–10, we note that we did not propose any additional edits in the FY 2021 IPPS/LTCH PPS proposed rule. Furthermore, we continue to believe that the ongoing MAC reviews of hospitals' Worksheet S–10 data coupled with our efforts to improve reporting through revised instructions, as well as providers' growing experience with reporting uncompensated care costs outweigh the value of any additional edits to the Worksheet S–10 data. Regarding the suggestion that we allow a 14-day time period for hospitals to submit corrections due to data mishandling, we will revisit the issue in future rulemaking as necessary, and further note that providers will have the opportunity to submit comments on the accuracy of the supplemental data files within 15 business days from the public display of this FY 2021 IPPS/LTCH PPS final rule.

Additionally, we recognize that a number of commenters suggested we audit all hospitals. In response to this, we note that the proposed uncompensated care payments to hospitals whose FY 2017 Worksheet S–10 data were audited represented approximately 65 percent of the proposed total uncompensated care payments for FY 2021, which is an increase from FY 2020 rulemaking in which about approximately half of total uncompensated care payments wereexpected to be made to hospitals whose FY 2015 Worksheet S–10 data had been audited. Further, while our

limited resources mean that it is not feasible to commit to auditing all hospitals every year, we note that we expect the number of audits will continue to increase from previous years. We are in the process of auditing FY 2018 data on an expanded number of hospitals.

In the FY 2021 IPPS/LTCH PPS proposed rule, we noted that given the unique nature of IHS and Tribal Hospitals and of the patient populations they serve, we believe it may be appropriate to restructure Medicare DSH payments and uncompensated care payments to these hospitals beginning in FY 2022. As discussed in prior rulemaking (for example, 82 FR 38188), the principal mission of the IHS is the provision of health care to American Indians and Alaska Natives throughout the United States. In carrying out that mission, IHS operates under two primary authorizing statutes. The first statute, the Snyder Act, authorizes IHS to expend such moneys as Congress may determine from time to time appropriate for the conservation of the health of American Indians or Alaska Natives. We refer readers to 25 U.S.C. 13 (providing that the Bureau of Indian Affairs (BIA) will expend funds as appropriated for, among other things, the conservation of health of American Indians and Alaska Natives); and 42 U.S.C. 2001(a) (transferring the responsibility for American Indian and Alaska Native health care from BIA to HHS). The second statute, the Indian Health Care Improvement Act (IHCIA), established IHS as an agency within the Public Health Service of HHS and provides authority for numerous programs to address particular health initiatives for American Indians and Alaska Natives, such as alcohol and substance abuse and diabetes (25 U.S.C. 1601 *et seq.*). IHS and Tribal hospitals are charged with addressing the health of American Indians and Alaska Natives and are uniquely situated to provide services to this population.

When Congress was considering reductions to the Medicare DSH payments and the creation of the Medicare uncompensated care payments under section 3133 the Affordable Care Act, one significant source of available information was the analysis done by the Medicare Payment Advisory Commission (MedPAC) in its March 2007 Report to the Congress. As discussed in the proposed rule, section 1886(r)(1) of the Act explicitly refers to this March 2007 Report to Congress as the basis for reducing DSH payments to 25 percent of the amount that would otherwise be paid under section 1886(d)(5)(F) of the Act. We have reviewed MedPAC's analysis in the March 2007 Report to Congress and it is not apparent that MedPAC was focused on the unique aspects of IHS and Tribal hospitals described previously when developing its recommendations for possible changes to DSH payments. Rather, it appears that MedPAC's analysis was focused on broader underlying issues and hospitals more generally.

Given the unique nature of IHS and Tribal hospitals, and the fact that we do not believe that the DSH analysis available to Congress at the time section 3133 of the Affordable Care Act was being developed was focused on the specific circumstances of these hospitals, in the FY 2021 IPPS/LTCH PPS proposed rule, we explained our belief that it may be appropriate, beginning in FY 2022, to use our authority under section 1886(d)(5)(I)(i) of the Act to create an exception for IHS and Tribal hospitals from Medicare DSH payments under 1886(d)(5)(F), as amended by section 3133 of the Affordable Care Act. This exception would also have the consequence that IHS and Tribal hospitals would be excluded from the calculation of Medicare uncompensated care payments under 1886(r). Concurrently, we believe it may be appropriate to use our authority under section 1886(d)(5)(I)(i) to adjust payments to IHS and Tribal hospitals through the creation of a new IHS and Tribal hospital Medicare DSH payment. The methodology for determining this IHS and Tribal hospital Medicare DSH payment would mirror the calculation of the Medicare DSH payment under 1886(d)(5)(F) except that the payment would be determined at 100 percent of the calculated amount rather than 25 percent of the calculated amount as required under section 3133 of the Affordable Care Act. We sought comment on this potential restructuring of the Medicare DSH and uncompensated care payments to IHS and Tribal hospitals beginning in FY 2022. We also noted that we intended to consider input received on this issue through consultation with IHS and Tribal hospitals.

Comment: In response to the discussion in the proposed rule of the unique circumstances of IHS and Tribal hospitals, commenters expressed support for the use of the low-income days proxy in the calculation of Factor 3 for FY 2021. In response to the request for comment on the potential restructuring of Medicare DSH and uncompensated care payments to these hospitals beginning in FY 2022, there were a few commenters that supported the creation of a new payment for IHS and Tribal hospitals consisting of 100 percent of the Medicare DSH amount. However, there were other commenters that requested that CMS provide more time so that the agency can consult with stakeholders on the proposed methodology. Specifically, a commenter requested that at a minimum, an additional year be given so that stakeholders can provide comments on the proposed policy and an additional three years as an implementation phase for the newly developed methodology, adding that an extension of the current proxy methodology would be needed.

Commenters also noted that only two IHS and Tribal hospitals, both of which, have more than 100 beds, would not be subject to the 12 percent cap on DSH payments. The commenters indicated that, in the event uncompensated care payments were to be determined using Worksheet S–10 data, instead of the low income days proxy, these two hospitals would see an increase in their uncompensated care payments, while the remaining 26 facilities would lose $7.5 million. These commenters recommended that CMS mitigate the effect of the cap under the statutory DSH calculation on IHS and Tribal facilities and if this is not possible, a commenter suggested that CMS should work with hospitals on a tailored methodology for the calculation of uncompensated care payments that fits their unique circumstances.

Further a commenter noted that IHS and Tribal Hospitals also face a unique legal standing such that they do not ''fit well into the framework that CMS is proposing to adjust for uncompensated care payments.'' The commenter also added that their inability to charge any Indian for services, even copays, and the provisions contained within treaties with the Federal Government and judicial rulings, means these hospitals face a very unique way of calculating uncompensated care costs and that the calculation of uncompensated care payments should be done in such a way as to maximize their access to federal resources. The commenter suggested that CMS should work with IHS and Tribal facilities as well as the consortium in providing guidance on how these facilities should report uncompensated care on Worksheet S–10. In this regard, another commenter pointed out that ''many tribal health programs invest non-Federal resources in their health care programs to furnish care that could easily be classified as uncompensated care because IHCPs [Indian Healthcare Providers] may not charge beneficiaries to receive care and, thus, typically do not have the

accounting methods to track these costs.'' This situation, according to the commenter, makes IHS and Tribal hospitals unable to report charity care and non-Medicare bad debt in a way that is consistent with the current definition of uncompensated care in the current regulation. Additionally, a commenter stated that the information technology systems used by the IHS and Tribal hospitals are not equipped to collect the necessary data for the Worksheet S–10 and that, while these systems have been upgraded, it will take some time, potentially years, before they are fully functional.

A few commenters also requested the continued use of the low-income days proxy in the calculation of Factor 3 for hospitals located in Puerto Rico. In particular, a commenter noted that they are working through challenges in implementing Worksheet S–10 and requested that CMS continue the use of low-income insured days to determine uncompensated care payments for Puerto Rico hospitals for at least another three years. Another commenter also requested that CMS treat Puerto Rico as it treats other states asserting that ''CMS does not include a proper count of low income Medicare beneficiaries that receive services in our hospitals'' [Puerto Rico hospitals]. The commenter asserts that CMS only accounts for low income Medicare beneficiaries in the SSI fraction for low income Medicare beneficiaries patients that live on the mainland but travel to Puerto Rico and require hospitalization.

Response: We appreciate the concerns raised by commenters regarding the calculation of Factor 3 for IHS and Tribal hospitals and hospitals located in Puerto Rico. We are not finalizing any policies for FY 2022 for these hospitals and will consider the issues raised by stakeholders in future rulemaking. For FY 2021, we are finalizing our proposal to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals. In regard to the comment concerning the data used in the SSI fraction for Puerto Rico hospitals, because we are continuing to use insured low-income patient days for uncompensated care in determining Factor 3 for FY 2021, and residents of Puerto Rico are not eligible for SSI benefits, we believe the SSI proxy consisting of 14 percent of a hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956) is still appropriate. In regard to the recommendation that we provide Puerto Rico hospitals a three-year continuation of the current policy before the transition to the use of Worksheet S–10, we invite commenters to provide further input as we revisit the use of Worksheet S–10 data from Puerto Rico hospitals in future rulemaking and assess the FY 2018 audit results from hospitals in Puerto Rico. We are not finalizing the proposal for Puerto Rico hospitals for FY 2022 and subsequent years, because we believe further consideration is necessary. However, we continue to believe Worksheet-S–10 data is the appropriate long term data source for hospitals located in Puerto Rico.

We also appreciate the concerns and input raised by commenters regarding alternative methodologies for the calculation of uncompensated care payments for IHS and Tribal hospitals. We recognize the unique nature of these hospitals and the special circumstances they face, and we reiterate our commitment to continue working with stakeholders, including through tribal consultation, as we revisit the issue of Medicare uncompensated care payments to these hospitals in the FY 2022 rulemaking. As discussed previously, we are not making any changes to the current policy for calculating uncompensated care payments for IHS and Tribal hospitals at this time, and we look forward to continuing to collaborate on methodological approaches in the future.

After consideration of the comments received, we are finalizing the use of low-income insured days proxy to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2021. We are not finalizing a methodology to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2022 and subsequent years at this time because we believe further consideration and review of these hospitals' Worksheet S–10 data is necessary.

(c) Definition of ''Uncompensated Care''

We continue to believe that the definition of ''uncompensated care'' first adopted in FY 2018 when we started to incorporate data from Worksheet S–10 into the determination of Factor 3 and that was used again in both FY 2019 and FY 2020 is appropriate, as it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, namely, charity care costs and bad debt costs, and correlates to Line 30 of Worksheet S–10. Therefore, we proposed that, for purposes of determining uncompensated care costs and calculating Factor 3 for FY 2021 and subsequent fiscal years, ''uncompensated care'' would continue to be defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). We refer readers to the FY 2020 IPPS/LTCH PPS rule (84 FR 42369 and 42370), for a detailed discussion of additional topics related to the definition of uncompensated care.

In the FY 2020 IPPS/LTCH PPS final rule, we stated that, we would attempt to address commenters' concerns regarding the Worksheet S–10 through future cost report clarifications to further improve and refine the information that is reported on Worksheet S–10 in order to support collection of the information necessary to implement section 1886(r)(2) of the Act. (84 FR 42370). In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32757), we noted that the Paper Reduction Act (PRA) package for Form CMS–2552–10 (OMB Control Number 0938–0050, expiration date March 31, 2022) would offer an additional opportunity to comment on the cost reporting instructions. For further information regarding PRA, we refer the reader to the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995*.

Comment: In regard to the definition of uncompensated care, several commenters urged CMS to include shortfalls from Medicaid, CHIP, and State and local indigent care programs, which, according to commenters, represent substantial losses as they do not fully cover the cost of providing care. A commenter noted that it is inconsistent that Medicaid patient data is used for DSH eligibility but not for the definition of uncompensated care and provided CMS with methodologies on how to account for Medicaid shortfalls, including specific modifications to Worksheet S–10, such as reporting Medicaid DSH payments on a separate line, separating stand-alone CHIP from the Medicaid line items, and reporting non-DSH supplemental payments separately from Medicaid revenue and Medicaid DSH. The stakeholder notes these suggestions were made in earlier rulemaking years, but not acted upon by CMS. A commenter also argued that including Medicaid shortfalls in Worksheet S–10 is especially important for hospitals in states that underwent Medicaid expansion, as compared to those that did not, which tend to do better with the current policy.

In contrast, a commenter noted that the unreimbursed portion of the costs of care furnished under state and local indigent care programs should be

specifically counted as charity care, while pointing out that Medicaid expansion has helped reduce hospital charity care. Some commenters believed Worksheet S–10 should be revised to better reflect the actual cost of caring for Medicaid patients incurred by hospitals (that is, net of Medicaid DSH payments and other supplemental funding).

Response: We appreciate commenters' suggestions for revisions and/or modifications to Worksheet S–10. We will consider the concerns raised by commenters as part of future cost report clarifications, and will make modifications as necessary, to further improve and refine the information that is reported on Worksheet S–10 to support collection of the information necessary to implement section 1886(r)(2) of the Act. With regard to the comments requesting that payment shortfalls from Medicaid and state and local indigent care programs be included in uncompensated care cost calculations, we recognize commenters' concerns but continue to believe there are compelling arguments for excluding such shortfalls from the definition of uncompensated care. For example, and as noted in past rulemaking, several key stakeholders, including MedPAC, do not consider Medicaid shortfalls in their definition of uncompensated care. Furthermore, we continue to believe that it is most consistent with section 1886(r)(2) of the Act for Medicare uncompensated care payments to target hospitals that incur a disproportionate share of uncompensated care for patients with no insurance coverage. In more practical terms, we also note that even if we agreed that it would be appropriate to adjust the definition of uncompensated care to include Medicaid shortfalls, this would not be a feasible option at this time due to computational limitations. Specifically, computing such shortfalls is operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid ''shortfalls.'' Therefore, it is not clear how CMS would determine how much of the ''shortfall'' is left after the Medicaid DSH payment is made. In addition, in some States, hospitals return a portion of their Medicaid revenues to the State via provider taxes and receive supplemental payments in return (along with the federal match), making the computation of ''shortfalls'' even more complex. Accordingly, after consideration of the comments received, and for the reasons discussed in the proposed rule and previously in this final rule, we are finalizing our proposal to continue to define uncompensated care costs as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

Comment: Commenters also suggested that CMS include all patient care costs when calculating the cost to charge ratio used in Worksheet S–10 including costs associated with training medical residents, supporting physician and professional services and paying provider taxes, so as to more accurately determine uncompensated care costs for purposes of the Worksheet S–10. Specifically, a commenter stated that the cost-to-charge ratio in line 1 does not include medical education costs and recommended that CMS include these costs, which they maintain can be derived from Worksheet B, column 24, line 118.

Response: As we have consistently stated in past final rules (84 FR 42378) in response to similar comments, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for other costs incurred, including costs associated with supporting and training physicians and other professionals or paying provider taxes associated with Medicaid, as commenters have suggested. In addition, because the CCR on Line 1 of Worksheet S–10 is obtained from Worksheet C, Part I, and is also used in other IPPS rate setting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude the costs associated with supporting physician and professional services and GME, we remain hesitant to adjust CCRs in the narrower context of calculating uncompensated care costs. Therefore, we continue to believe that it is not appropriate to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include any additional costs in the numerator of the CCR calculation.

Comment: A few commenters requested that implicit price concessions be included in the definition of uncompensated care. Specifically, commenters expressed concern that without clear reporting instructions, implicit price concessions may no longer be included in Worksheet S–10 as bad debt and requested that CMS clarify that they should be considered as bad debt and must be included on the Medicare cost report. A commenter also expressed concern that CMS's requirement that hospitals write off Medicare beneficiary accounts that meet a hospital's financial assistance policy to bad debt, rather than charity care, causes their uncompensated care payments to be reduced because these implicit price concessions are multiplied by the hospital's cost to charge ratio (CCR), which is inconsistent with general accounting practices and could cause distortion in the distribution of uncompensated care payments.

Response: We appreciate commenters' input in regard to CMS's proposed policy on implicit price concessions and bad debt and the implications for Worksheet S–10 reporting. For further discussion and clarification on this topic, we refer readers to the bad debt section in this final rule. We note that the final bad debt policy related to implicit price concessions that we are adopting this final rule will be prospectively effective for cost reporting periods beginning on or after October 1, 2020.

Comment: Some commenters raised the use of presumptive eligibility tools in the determination of patient charity care, arguing that such tools offer an efficient and accurate way to determine uncompensated care costs. Specifically, commenters stated that the issue is that the MACs disallow charity care granted using such tools, adding that CMS should clarify that providers may indeed utilize presumptive eligibility as indicator of charity care and encouraged the agency to expedite updating the Provider Reimbursement Manual to clarify this issue.

Response: We appreciate commenters' input on this issue. With regard to the comments regarding the use of presumptive eligibility tools to determine charity care, we note that CMS does not set charity care criteria policy for hospitals, and within reason, hospitals can establish their own criteria for what constitutes charity care in their charity care and/or financial assistance policies. We refer the reader to the section IX.C (Revisions of Medicare Bad Debt Policy) of this preamble for related discussion of presumptive eligibility tools. We note that the forthcoming Paper Reduction Act (PRA) package for Form CMS–2552–10 (OMB Control Number 0938–0050, expiration date March 31, 2022) offers an additional opportunity for hospitals and other stakeholders to comment on the cost reporting instructions.

Comment: A few commenters requested additional information from CMS on how payments furnished by Congress, as well as payments made by the Health Resources and Services Administration (HRSA) for uninsured

COVID–19 patients will be treated, pointing out that such payments may not necessarily offset uncompensated care, but, rather, were intended to cover the costs of responding to the COVID–19 PHE. To this end, another commenter noted funding provided by the Department of Health and Human Services (HHS) ''in the general distribution, high-impact distribution, safety net distribution, and other allocations funded via the CARES Act would not be an offset specifically to uncompensated care.''

Response: We recognize commenters' concerns regarding the unique situation posed by the COVID–19 PHE in the reporting of uncompensated care costs. We will consider these concerns as appropriate in developing future reporting guidance. General information on the CARES Act Provider Relief Fund is available at: *https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html*. Information regarding HRSA COVID–19 and information on the HRSA Uninsured Program is available at: *https://coviduninsuredclaim.linkhealth.com/*. We note that a term and condition of the HRSA Uninsured Program is the following ''The Recipient will not include costs for which Payment was received in cost reports or otherwise seek uncompensated care reimbursement through federal or state programs for items or services for which Payment was received.''

The following comments relate to the Worksheet S–10 instructions:

Comment: In regard to Worksheet S–10 instructions and guidance, several commenters commended CMS for its refinements to Worksheet S–10 in November 2016 (Transmittal 10) and for its continued efforts to improve the accuracy of the reported data, indicating that the instructions have improved. However, many commenters still requested that CMS clarify instructions to the Worksheet S–10 in areas where the treatment of uncompensated care costs (charity care and bad debt) is not immediately clear based on the revised instructions. A commenter suggested that CMS should engage MACs and hospitals prior to the release of substantial revisions to cost report instructions, which, according to the commenter, would promote dialogue on best reporting practices; similarly, another commenter suggested that CMS conduct additional outreach for stakeholder feedback and education before making revisions to Worksheet S–10 instructions.

One common issue raised by commenters was a request that CMS improve the instructions so that non-Medicare bad debt is not multiplied by the cost-to-charge ratio. According to a commenter, applying the cost to charge ratio to non-Medicare bad debt is not mathematically sound nor does it represent a hospital's true cost. Another commenter indicated that such practice is also inconsistent with the way non-reimbursable Medicare bad debt is treated. To address this, commenters suggested that CMS establish separate columns in Worksheet S–10 for insured and uninsured bad debt, where the column for insured bad debt is not multiplied by the CCR and the column for uninsured bad debt is multiplied by the CCR, as is currently done with charity care.

Another suggestion was that CMS insert two new columns before column 2 in the Worksheet S–10 to enable hospitals to separately report charges subject the CCR. According to the commenter, such a structure would be needed for lines 20 and 21 but not for lines 22 and 23; per the commenter's recommendation, CMS would be able to discontinue lines 24 and 25, given that those amounts would be obsolete under the commenter's recommended restructuring of the worksheet. Further, the commenter requested that CMS clarify whether the wording ''total facility except physician and other professional services,'' in relation to charity care and bad debt write-offs is inclusive of acute inpatient, exempt inpatient, outpatient, and long-term care services. The commenter also sought clarification of the definition of ''non-covered'' charges related to days exceeding the length of stay limit and with respect to Medicare, Medicaid, Workers' Compensation/No Fault, and commercial plans with which the hospital has a contractual relationship, but is not allowed to pursue patient collections for losses (for example, unpaid claims). In addition, the commenter sought clarification on whether a hospital is permitted to include such losses on Line 20, if it includes them in its financial assistance policy.

Finally, a commenter inquired if there were any templates under review for reporting charity care, uninsured discounts, and/or bad debt listings and, if so, the status of any such templates. The commenter also recommended that CMS should require the total bad debt listing to be submitted and reconciled with Worksheet S–10 line 26.

Response: We appreciate commenters' concerns regarding the need for clarification of the Worksheet S–10 instructions, as well as their suggestions for form revisions to improve provider reporting. We reiterate our commitment to continuing to work with stakeholders to address their concerns regarding Worksheet S–10 instructions and reporting through provider education and further refinement of the instructions as appropriate. As noted by some commenters, such continued efforts to refine the instructions and guidance have improved provider understanding of the Worksheet S–10. We also recognize that there are continuing opportunities to further improve the accuracy and consistency of the information that is reported on the Worksheet S–10, and to the extent that commenters have raised new questions and concerns regarding the reporting requirements, we will attempt to address them through future rulemaking and/or sub-regulatory guidance. However, we also continue to believe that the Worksheet S–10 instructions are sufficiently clear to allow hospitals to accurately complete Worksheet S–10. Regarding the comments requesting specific structural changes to Worksheet S–10 and/or further clarification of the reporting instructions, we note that these comments fall outside the scope of this final rule. We therefore refer commenters to the forthcoming Paper Reduction Act (PRA) package for the Worksheet S–10, which will include a public comment period and will be the appropriate forum to raise specific questions about or suggestions for modifications to Worksheet S–10, including the reporting instructions.

Additionally, we refer commenters to the updated instructions for Worksheet S–10 that were issued in November 2016 through Transmittal 10, as well as those issued in September 2017 through Transmittal 11, in which we specifically clarified the definitions of and the instructions for reporting uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, charity care, and modified the calculations relative to uncompensated care costs as well as added edits to improve the integrity of the data reported on Worksheet S–10.

For commenters' reference, additional materials regarding clarifications to the Worksheet S–10 instructions are contained in the MLN article titled ''Updates to Medicare's Cost Report Worksheet S–10 to Capture Uncompensated Care Data'', available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17031.pdf* as well as the Worksheet S–10 Q&As on the CMS DSH website in the download section, available at: *https://www.cms.gov/Medicare/*

Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Worksheet-S-10-UCC-QandAs.pdf.

(d) Changes to the Methodology for Calculating Factor 3 for FY 2021 and Subsequent Fiscal Years

The proposed changes to the methodology for calculating Factor 3 that were discussed in the IPPS/LTCH PPS proposed rule include the following:

- *Merger Multiplier for Acquired Hospital Data*

In the FY 2015 IPPS/LTCH PPS final rule, we defined a merger as an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider (79 FR 50020). In that final rule, we adopted a policy for calculating Factor 3 for hospitals that undergo a merger during or after the time period of the data that is used in the Factor 3 calculations, as well as a separate policy for a merger that occurs after the development of the final rule for the applicable fiscal year. Our proposed policy for newly merged hospitals is discussed in the next section. In the FY 2019 IPPS/LTCH PPS final rule, we finalized a policy for determining the uncompensated care costs of hospitals that have multiple cost reporting periods starting in the same fiscal year of using the longest cost report beginning in the applicable fiscal year and annualizing the uncompensated care data if a hospital's cost report does not equal 12 months of data (83 FR 41427). This policy applied for all hospitals, including those involved in a merger. However, taking into consideration past comments regarding mergers, including comments on the FY 2019 IPPS/LTCH PPS proposed rule which suggested that we not annualize the uncompensated care costs data provided in short cost reporting periods for acquired hospitals because their uncompensated care costs for the remaining part of the year are included in the new combined hospital's cost report (83 FR 41427), we proposed to modify the annualization policy that was finalized in FY 2019 with respect to merged hospitals.

We noted that for most mergers, the effective date of the merger coincides with the cost reporting end date for the hospital that is being acquired. In effect, this means that the FY 2015 merger policy of combining uncompensated care costs (UCC) across CCNs results in adding together data reported on the cost report for two different CCNs (the acquired hospital and the surviving hospital) to estimate the merged hospital's post-merger total UCC. For mergers with a recent merger effective date, such as a merger in Federal fiscal year 2019 (that is, a merger after the period of the FY 2017 cost reports we proposed to use for the Factor 3 calculation), we stated that we continue to believe the current policy of annualizing and combining across historical cost reports produces the best available estimate for post-merger total UCC. For example, if the acquired hospital's FY 2017 cost report includes less than 12 months of data, we would annualize the data to reflect a full 12 months of data. Similarly, in this example, if the surviving hospital's cost report includes less than 12 months of data, we would annualize its uncompensated care data. However, as discussed later in this section, we proposed a modification to this policy when the merger effective date occurs partway through the surviving hospital's cost reporting period.

In some mergers, the merger effective date does not coincide with the start date for the surviving hospital's cost reporting period. When the merger effective date does not coincide with the start date of the surviving hospital's cost reporting period, the policy of annualizing the acquired hospital's data before combining data across hospital cost reports could substantially overestimate the acquired hospital's UCC, given that the surviving hospital's cost report reflects the UCC incurred by the acquired hospital during the portion of the year after the merger effective date. In other words, when the merger effective date is partway through the surviving hospital's cost reporting period, annualizing the acquired hospital's data may double-count UCC for the portion of the year that overlaps with the remainder of the surviving hospital's cost reporting period.

Accordingly, to more accurately estimate UCC for the hospitals involved in a merger when the merger effective date occurs partway through the surviving hospital's cost reporting period, we proposed not to annualize the acquired hospital's data. Further, we proposed to use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. Specifically, we proposed to calculate a multiplier to be applied to an acquired hospital's UCC when the merger effective date occurs partway through the surviving hospital's cost reporting period. This multiplier would represent the portion of the UCC data from the acquired hospital that should be incorporated with the surviving hospital's data to determine UCC for purposes of determining Factor 3 for the surviving hospital. This multiplier is obtained by calculating the number of days between the start of the applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. Applying this multiplier to the acquired hospital's unannualized UCC data would determine the final portion of the acquired hospital's UCC that should be added to that of the surviving hospital for purposes of determining Factor 3.

As an example, if the cost reporting period start dates of the acquired and surviving hospitals align and a merger occurs halfway through the surviving hospital's cost reporting period (for example, the hospital's fiscal year), then ultimately, the cost report for the surviving hospital for that fiscal year would already reflect half a year of the acquired hospital's UCC (because the merger occurred halfway through the surviving hospital's cost reporting period and the UCC data reported by the surviving hospital incorporate any UCC incurred by the acquired hospital during the second half of the fiscal year). For illustrative purposes, consider that the cost reporting period start dates of the acquired and surviving hospitals are 10/01/2016; the cost reporting period end date of the acquired hospital is 06/30/2017; and the merger acquisition date is 07/01/2017. Thus, there are 273 days between the start of the cost reporting period of the surviving hospital and the merger effective date, and the cost reporting period of the acquired hospital is 273 days. The multiplier, as previously defined, would be 1 (273 days divided by 273 days) and all of the acquired hospital's unannualized UCC data for the period 10/01/2016 to 06/30/2017 would be added to that of the surviving hospital for purposes of calculating Factor 3 for FY 2021. It is not necessary to annualize the acquired hospital's data from its short cost report, because the UCC incurred by the acquired hospital for the remainder of the surviving hospital's fiscal year post-merger (07/01/2017 to 09/30/2017) are already included in the UCC data reported by the surviving hospital for the cost reporting period ending on 09/30/2017.

As another example, we assumed the merger effective date was the same as the start date for the surviving hospital's cost reporting period and the surviving hospital's cost reporting period is 12 months long. In this example, we explained our belief that it would not be

necessary to combine uncompensated care costs across multiple cost reports, because the surviving hospital's cost report already reflects 12 months of uncompensated care costs for the merged hospital. In this example, the multiplier would be 0 because there are 0 days between the start of the surviving hospital's cost reporting period and the merger effective date, and there would be no need to combine data from the acquired hospital given that the surviving hospital's cost report reflects all post-merger UCC data for the acquired hospital.

• *Newly Merged Hospitals*

We proposed to continue to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year would be recalculated similar to new hospitals (79 FR 50021 and 50022).

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, we proposed to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment would be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 would be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, we proposed that the data from the newly merged hospital's cost report would be annualized for purposes of the Factor 3 calculation. We noted that we were not proposing that the multiplier calculation discussed previously would be used, as that would only be necessary for estimating post-merger data using historical reports. The acquired hospital's uncompensated care payment for the fiscal year during which the merger occurs would be determined using the prospectively determined Factor 3 amount for the acquired hospital and then prorated, if applicable. We referred readers to the detailed discussion in the FY 2015 IPPS/LTCH PPS rule regarding the calculation of pro rata uncompensated care payments (79 FR 50151 through 50153).

Consistent with past policy, we also proposed that the interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available the time of the development of the final rule. In other words, for FY 2021, the eligibility of a newly merged hospital to receive interim uncompensated care payments and the amount of any interim uncompensated care payments, would be based only on the FY 2017 cost report available for the surviving CCN at the time the final rule is developed. However, at cost report settlement, we would determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2021 cost report. That is, we would revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2021 cost report.

Comment: A few commenters supported CMS's policy proposal for combining uncompensated care costs data in the case of mergers by using a multiplier to adjust the acquired hospital's data. A commenter also supported the proposed policy regarding the treatment of mergers that happen after the final rule is issued. Another commenter, who expressed support for the annualization of uncompensated care costs from cost reports containing less than 12 months of data for the purpose of calculating Factor 3, also supported CMS's proposal to annualize the surviving newly merged hospital's cost report data for purposes of determining that hospital's proportion of uncompensated care.

Response: We appreciate the support for our proposal to apply a multiplier to the acquired hospital's unannualized uncompensated care cost data to determine the final portion of the acquired hospital's uncompensated care costs that should be added to the uncompensated care costs of the surviving hospital for purposes of determining Factor 3. We also appreciate support for the proposal to treat hospitals that merge after the final rule has been issued as new hospitals. Additionally, we appreciate the support for our policy of annualizing the data from cost reports that do not include 12 months of data, including our proposal to annualize the data for surviving newly merged hospitals if their cost reporting period does not equal 12 months.

• *Annualization and Long Cost Reports*

We proposed to continue the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data, except in the case of mergers, which would be subject to the modified merger policy previously discussed. In addition, we proposed to continue the policies that were finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41415) regarding the use of the longest cost report available within the Federal fiscal year. However, we proposed to modify our current policy for those rare situations where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. Under this proposal, we would use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data for the latter fiscal year is used in the Factor 3 methodology. The current policy for this rare situation includes the criterion that the hospital have multiple cost reports beginning in the same fiscal year. However, we explained that we no longer believe this is a necessary condition, given that we have identified some hospitals that have no FY 2017 cost report, but that only have one FY 2016 cost report, which spans the entire FY 2017 period.

Comment: Some commenters supported the continuation of annualization and the proposed modification to the long cost report policy.

Response: We appreciate the support for our proposals. We are finalizing as proposed.

• *New Hospital for Purposes of Factor 3*

We proposed to continue the new hospital policy that was finalized in the FY 2020 IPPS/LTCH PPS final rule. Specifically, for new hospitals that do not have an FY 2017 cost report to use in the Factor 3 calculation (that is, hospitals with CCNs established on or after October 1, 2017) that may have a preliminary projection of being eligible for DSH payments based on their most recent available disproportionate patient percentage, we proposed that the MAC would make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2021 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for

FY 2021, the hospital would receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2021 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2017 cost reports for all DSH-eligible hospitals. This denominator would be the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals, with the exception of Puerto Rico hospitals and IHS and Tribal hospitals. The new hospital would not receive interim uncompensated care payments before cost report settlement because we would have no FY 2017 uncompensated care data on which to determine what those interim payments should be.

Comment: Commenters supported this proposal for continuing the new hospital policy.

Response: We thank the commenters for their support. We are finalizing as proposed, without modification.

- *IHS and Tribal Hospitals*

For the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), we continue to recognize that the use of data from Worksheet S–10 to calculate the uncompensated care amount for IHS and Tribal hospitals for FY 2021 may jeopardize these hospitals' payments due to their unique funding structure. Prior to the proposed rulemaking for FY 2021, CMS consulted with IHS and Tribal hospitals regarding Worksheet S–10 uncompensated care reporting as well as any potential barriers under the current cost reporting instructions to reporting by IHS and Tribal hospitals on Worksheet S–10. During the consultation, representatives of some hospitals indicated that it was not clear to them that they could submit Worksheet S–10 data given the historical use of the low-income patient proxy when determining Factor 3 for these hospitals. CMS reiterated that the use of the low-income patient proxy when determining Factor 3 does not preclude the submission of Worksheet S–10 data by these hospitals. CMS explained that IHS and Tribal Hospitals should be aware of and comply with the instructions and requirements for the submission of Worksheet S–10 data. We noted that an o the MLN Matters® Special Edition article ''Updates to Medicare's Cost Report Worksheet S–10 to Capture Uncompensated Care Data'' that was released on September 29, 2017, provides an overview of the instructions and requirements for reporting on the Worksheet S–10 and is available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17031.pdf*. Another source of information is the ''Worksheet S–10—Hospital Uncompensated and Indigent Care Data Following 2018 IPPS Final Rule Questions and Answers'' that is also available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Worksheet-S-10-UCC-QandAs.pdf*. As discussed previously in this section, we also noted that CMS continues to consider the feedback provided during IHS and Tribal consultation for purposes of determining what policies should apply with respect to DSH and uncompensated care payments to IHS and Tribal hospitals in future years and solicited comment on this issue to assist future rulemaking. We also noted that the Paper Reduction Act (PRA) package for Form CMS 2552–10 will be an additional opportunity for comments on the Worksheet S–10 instructions.

Therefore, for IHS and Tribal hospitals that have a FY 2013 cost report, we proposed to continue the policy first adopted for the FY 2018 rulemaking regarding the low-income patient proxy. Specifically, for FY 2021 we proposed to determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent update of SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. We explained that we continue to believe this approach is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a HCRIS extract updated through February 19, 2020, and the most recent available FY 2018 SSI days.

We refer the reader to the previous section for a discussion regarding comments related to IHS and Tribal hospitals. We are finalizing the above methodology for IHS and Tribal hospitals for FY 2021 as proposed without modification.

- *Puerto Rico Hospitals*

In the FY 2021 IPPS/LTCH PPS proposed rule, we explained that we had considered calculating the Factor 3 amounts for Puerto Rico hospitals for FY 2021 using the same methodology we proposed for hospitals other than IHS and Tribal hospitals. However, we concluded that the recent natural disasters in Puerto Rico may negatively impact the ability of these hospitals to engage in the FY 2021 rulemaking on the particular issue of the data to be used to determine Factor 3 for Puerto Rico hospitals, while simultaneously focusing on ensuring that their FY 2018 uncompensated care Worksheet S–10 data is accurately reported and available for use in calculating FY 2022 Medicare uncompensated care payments consistent with our proposed approach for FY 2022 and subsequent fiscal years.

Accordingly, for FY 2021 we proposed to determine Factor 3 for Puerto Rico hospitals that have a FY 2013 cost report based on the low-income patient proxy. We would determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent update of SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. We continue to believe the use of FY 2013 data in determining the low-income insured days proxy is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a recent HCRIS extract and the most recent available FY 2018 SSI days. In addition, because we proposed to continue to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we proposed to continue to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

We refer the reader to the previous section for a discussion regarding comments related to Puerto Rico hospitals. We are finalizing the above methodology for Puerto Rico hospitals for FY 2021 as proposed without modification.

• *All-Inclusive Rate Providers*

In FY 2018 IPPS/LTCH PPS final rule (82 FR 38218), we indicated that we would further explore which trims are appropriate to apply to the CCRs on Line 1 of Worksheet S–10, including whether it is appropriate to apply a unique trim to certain subsets of hospitals, such as all-inclusive rate providers. We noted that all-inclusive rate providers have the ability to compute and enter their appropriate CCR on Worksheet S–10, Line 1, by answering Yes to the question on Worksheet S–2, Part I, Line 115, and not have it computed using information from Worksheet C, Part I. We stated that we would give more consideration to the utilization of statewide averages in substituting outlier CCRs, and that we intended to consider other approaches that would ensure validity of the trim methodology and not penalize hospitals that use alternative methods of cost apportionment in future rulemaking. In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19420), we stated that we had examined the CCRs from the FY 2015 cost reports and believed the risk that all-inclusive rate providers will have aberrant CCRs and, consequently, aberrant uncompensated care data, was mitigated by the proposal to apply the trim methodology for potentially aberrant uncompensated care costs to all hospitals.

In preparation for the FY 2021 rulemaking, we conducted a review of the CCRs from the FY 2017 cost reports from all-inclusive rate providers (AIRPs) and determined that in rare situations they may include a potentially aberrant CCR (Worksheet S–10 line 1) which results in a ratio of total UCC to total operating costs of greater than 50 percent. For FY 2021, we continue to believe that all-inclusive rate providers should be excluded from the CCR trim methodology because all-inclusive rate providers have alternative methods of cost apportionment that are different from those used in the standard CCR calculation. However, in order to ensure that we are able to calculate a reasonable estimate of the hospital's FY 2017 UCC, we proposed to modify the potentially aberrant UCC trim methodology when it is applied to all-inclusive rate providers. Specifically, we proposed that when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its FY 2017 cost report, we would recalculate UCC using the CCR reported on Worksheet S–10, line 1 of the hospital's most recent available prior year cost report that would not result in UCC of over 50 percent of total operating costs. That is, we would apply the CCR from Worksheet S–10 line 1 of that prior cost report to the data reported on Worksheet S–10 of the FY 2017 cost report. For purposes of the proposed rule, we identified a few AIRPs that had UCC in excess of 50 percent of their total operating costs. For these hospitals, we used the CCR from Worksheet S–10, line 1 of their FY 2015 cost report in place of the CCR reported on Worksheet S–10, line 1 of their FY 2017 cost report, in order to re-calculate their UCC. As we explained in the proposed rule, we believe this approach produces a more accurate estimate of the AIRP's UCC for purposes of determining Factor 3, while continuing to reflect the information on uncompensated care included in the AIRP's FY 2017 cost report, which for the reasons discussed previously we believe is the most appropriate data to be used in determining Factor 3 for FY 2021.

Comment: A commenters supported this proposal related to AIRPs.

Response: We thank the commenter for their support.

• *CCR Trim Methodology*

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). Similar to the process used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38218), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415 and 41416), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42372) for trimming CCRs, we proposed the following steps to determine the applicable CCR:

Step 1: Remove Maryland hospitals. In addition, we would remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: For FY 2017 cost reports, calculate a CCR ''ceiling'' with the following data: For each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we would use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report would be selected.) The ceiling would be calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2017 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15. (As explained in the proposed rule, this is not a change from the methodology used in past years. In past rules, we inadvertently referred to Column 14, rather than Column 15.)

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for FY 2017 greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For the proposed rule, the statewide average CCR was applied to 12 hospitals, of which 4 hospitals had FY 2017 Worksheet S–10 data. (For this final rule, the statewide average CCR was applied to 13 hospitals, of which 3 hospitals have FY 2017 Worksheet S–10 data.)

Step 5: For providers that did not report a CCR on Worksheet S–10, Line 1, we would assign them the statewide average CCR as determined in step 3.

We proposed that after completing the described previously steps, we would re-calculate the hospital's uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

Comment: In relation to the proposed CCR trim methodology a commenter requested that CMS reconsider its policy of applying the state-wide average CCR for providers with a CCR above the proposed ceiling. The commenter suggested an alternative approach of using the hospital's previous CCR or an average of two or three years CCRs to reflect the provider's actual experience. Another commenter supported CMS's proposed policy of excluding All-Inclusive Rate Providers (AIRPs) from the CCR trim methodology and agreed with CMS's proposed approach of assessing whether the amount of uncompensated care resulting from the product of the AIRP-reported CCR and uncompensated care charges is greater than 50 percent of total operating costs; in such cases, CMS proposed to use the CCR from the 2015 Worksheet S–10, which, according to a commenter, the agency has already vetted.

Response: We appreciate the comments regarding the proposed CCR trim methodology. We believe that the

suggested alternative approaches to the use of the statewide average CCR for providers with a CCR above the CCR ''ceiling'', including using a hospital's previous CCR or an average of multiple CCRs, may not provide a solution as some providers may still have high CCRs in the past fiscal years. Further, we note that the proposed CCR trim methodology is not only similar to the CCR trim methodology policy that has been used for purposes of determining uncompensated care payments since FY 2018, but is also consistent with the approach used in the outlier payment methodology under § 412.84(h)(3)(ii), which states that the Medicare contractor may use a statewide average CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean.

- Uncompensated Care Data Trim Methodology

In the proposed rule, we noted that after applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant data that are unrelated to its CCR. Therefore, we proposed to continue the trim methodology for potentially aberrant UCC that was finalized in the FY 2019 and FY 2020 IPPS/LTCH PPS final rules. That is, if the hospital's uncompensated care costs for FY 2017 are an extremely high ratio (greater than 50 percent) of its total operating costs, we proposed to determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and to apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. Specifically, if the FY 2017 cost report is determined to include potentially aberrant data, we proposed that data from the FY 2018 cost report would be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2017 would be trimmed by multiplying its FY 2017 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2018 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2017 for purposes of determining Factor 3 for FY 2021.

However, because we have audited the FY 2017 Worksheet S–10 data for a number of hospitals, we explained our belief that it is necessary to modify the UCC data trim methodology for hospitals whose FY 2017 cost report has been audited. Because the UCC data for these hospitals have been subject to audit, we believe there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, we stated that we no longer believe it is necessary to apply the trim methodology for these audited hospitals. Accordingly, we proposed to exclude hospitals that were part of the audits from the trim methodology for potentially aberrant UCC. For those hospitals that do not have audited Worksheet S–10 data, we proposed to continue to apply the trim methodology as previously described.

Comment: A few commenters expressed support for the proposal to substitute extremely high uncompensated care costs with information from FY 2018 cost reports and supported the agency's proposed modification to the uncompensated care data trim methodology to exempt hospitals for which uncompensated care values have been audited from the application of the uncompensated care cost adjustment.

Response: We appreciate the comments regarding our proposed policy for trimming uncompensated care costs that are an extremely high ratio of a hospital's total operating costs for the same year. We believe the proposed approach balances our desire to exclude potentially aberrant data with our concern regarding inappropriately reducing FY 2021 uncompensated care payments to a hospital that may have a legitimately high ratio as determined through an audit of their Worksheet S–10 data.

- Summary of Proposed Methodology

In summary, for FY 2021, we proposed to compute Factor 3 for each hospital using the following steps—

Step 1: Select the provider's longest cost report from its Federal fiscal year (FFY) 2017 cost reports. (Alternatively, in the rare case when the provider has no FFY 2017 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2017 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy, discussed earlier.

Step 4: Calculate Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculate Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2017 cost report data (from Step 1, 2 or 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We proposed to amend the regulation at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*7*) to reflect the methodology for computing Factor 3 for FY 2021. We also proposed to add a new paragraph (g)(1)(iii)(C)(*8*) to reflect the proposal for all subsequent fiscal years to use the most recent available single year of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals, except IHS and Tribal hospitals.

Comment: Some commenters urged CMS to consider a five to ten percent stop-loss policy across all hospitals' uncompensated care payments, so as to help mitigate and minimize hospital uncompensated care payment fluctuations across years.

Response: As discussed in last year's final rule (84 FR 42366) and prior rulemaking, section 1886(r) does not provide CMS with authority to implement a stop-loss policy. Rather, section 1886(r)(2)(C) requires that we determine Factor 3 for each hospital based upon the ratio of the amount of uncompensated care furnished by the hospital compared to the uncompensated care furnished by all DSH-eligible hospitals, and there is no authority under section 1886(r) to adjust this amount. We note that the use of three years of data to determine Factor 3 for FY 2018 and FY 2019, as discussed in the FY 2020 IPPS/LTCH PPS final rule already provided a mechanism that had the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data. However, we will continue to monitor uncompensated care payments for payment fluctuations as we move forward with using only one year of Worksheet S–10 for future Factor 3 calculations.

Comment: A commenter recommended that CMS use the traditional payment reconciliation process to calculate final payments for uncompensated care costs pursuant to section 1886(r)(2) of the Act. The commenter did not object to CMS using

prospective estimates, derived from the best data available, to calculate interim payments for uncompensated care costs. However, the commenter stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the Federal fiscal year. The commenter also noted that not all FY 2017 Worksheet S–10 cost reports were audited and that the use of this blend of audited and unaudited data would be arbitrary and consistent with the statutory requirements. This same commenter also expressed the need for meaningful engagement on concerns raised in the rulemaking process, and stated that the preclusion of review provision leaves intact the agency's responsibilities, including the rulemaking requirements of the Administrative Procedure Act and the Medicare Act.

Response: Consistent with the position that we have taken in rulemaking for previous years, we continue to believe that applying our best estimates of the three factors used in the calculation of uncompensated care payments to determine payments prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; 82 FR 38195; and 84 FR 42373). We believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenter's suggestion that we should establish a process for reconciling our estimates of uncompensated care payments, which would be contrary to the notion of prospectivity. Furthermore, we note that this rulemaking has been conducted consistent with the requirements of the Administrative Procedure Act and Title XVIII of the Act. Under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2021 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed methodology for calculating Factor 3 and the data that would be used. We made public the best data available at the time of the proposed rule, in order to allow hospitals to understand the anticipated impact of the proposed methodology and submit comments, and we have considered those comments in determining our final policies for FY 2021.

After consideration of the public comments we received, and for the reasons discussed in the proposed rule and in this final rule, for FY 2021, we are finalizing the following methodology to compute Factor 3 for each hospital by—

Step 1: Selecting the provider's longest cost report from its Federal fiscal year (FFY) 2017 cost reports. (Alternatively, in the rare case when the provider has no FFY 2017 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2017 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualizing the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combining adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy, discussed earlier.

Step 4: Calculating Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculating Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2017 cost report data (from Step 1, 2 or 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We also are finalizing without modification the other proposals related to the Factor 3 methodology that are discussed in this section.

For this FY 2021 IPPS/LTCH PPS final rule, we are finalizing a HCRIS cutoff of June 30, 2020, for purposes of calculating Factor 3, except in rare situations where report upload discrepancies by CMS or the MACs have been corrected, as appropriate. We are also finalizing our proposal to amend the regulations at § 412.106(g)(1)(iii)(C) by adding new paragraphs (7) and (8) to reflect the methodology for computing Factor 3 for FY 2021 and for subsequent fiscal years. In brief, the methodology adopted in this final rule for purposes of determining Factor 3 would apply for FY 2022 and subsequent years, using Worksheet S–10 data from the most recent cost reporting year for which audits have been conducted.

(e) Proposals Related to the Per Discharge Amount of Interim Uncompensated Care Payments

Consistent with the policy adopted in FY 2014 and applied in each subsequent fiscal year, we proposed to use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount, is divided by the hospital's historical 3-year average of discharges computed using the most recent available data. The result of that calculation is a per discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH eligible hospital. The interim uncompensated care payments made to the hospital during the fiscal year are reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the Federal fiscal year.

In response to our proposal in the FY 2020 IPPS/LTCH PPS proposed rule to continue to determine interim uncompensated care payments using a 3-year average of discharges, we received a comment expressing concern that discharge growth discrepancies create the risk of overpayments of interim uncompensated care payments and unstable cash flows for CMS, hospitals, and MA plans (84 FR 42373). Taking the commenter's concerns into consideration, for FY 2021, we proposed a voluntary process through which a hospital may submit a request to its Medicare Administrative Contractor (MAC) for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital would be required to provide supporting documentation demonstrating there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount were not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its

per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

We proposed that the hospital's MAC would evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the 3-year average of discharges is lower than hospital's projected FY 2021 discharges. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that would be made would be to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, this proposal would not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

Comments: A few commenters recognized the effort CMS has taken in addressing uncompensated care overpayments. These commenters expressed support for the proposal to provide an option for hospitals to submit a request to their MAC for a lower interim uncompensated care payment. The commenters noted that the policy would mitigate discharge growth discrepancies that could lead to an overestimate of the per-discharge amount of interim uncompensated payments, which could cause unstable cash flows for hospitals.

In contrast, a commenter stated that it seemed unlikely hospitals would want to request lower or zero per-claim uncompensated care payments because of inherent incentives to maximize their cash flow. The commenter also noted that the current claims average does not consider the growth in Medicare eligibility since 2019 due to the aging of baby boomers. This lack of consideration, according to the commenter, results in the risk of overpayments for uncompensated care and unstable cash flows for hospitals and MA plans. To minimize this risk, the commenter suggested a growth factor, based on the CBO estimate of 64 million Part A fee- for-service beneficiaries in 2021 compared to the 61 million in 2019, be applied to the three-year claims average (that is, a growth factor of 1.05 (64/61)).

The commenter also expressed concern that exorbitant amounts in per-claim uncompensated care payments could result in surprise balance billing if MA beneficiaries use an out-of-network provider, where coinsurance payments could range from 20 percent to 40 percent. To avoid this situation, the commenter recommended that CMS place a cap on per-discharge uncompensated care payments ''within the range of $6,232—$12,464, which represents a range of one to two standard deviations of the Estimated Per Claim Amounts for all qualifying hospitals.''

Response: We thank commenters for their thoughtful suggestions regarding our proposal to allow hospitals the opportunity to voluntarily request a decrease to their per-claim uncompensated care payments. We are finalizing the policy as proposed without modification, because we believe the policy may facilitate greater payment predictability throughout the year and limit recoupment of overpayments as part of cost report settlement. We will consider commenters' input and suggestions regarding this policy in considering any potential modifications or refinements to this policy in future rulemaking.

(f) Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this final rule, we will publish on the CMS website a table listing Factor 3 for all hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2021 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. We note that, at the time of development of this final rule, the FY 2018 SSI ratios were available. Accordingly, we computed Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the most recent available data regarding SSI days from the FY 2018 SSI ratios.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital.

Hospitals had 60 days from the date of public display of the FY 2021 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of the Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling or most recent report differs from previously accepted amended report due to MAC mishandling). We stated that comments that are specific to the information included in the table and supplemental data file could be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We indicated we would address these comments as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2020 IPPS/LTCH PPS final rule.

For FY 2021, we proposed that after the publication of the FY 2021 IPPS/LTCH PPS final rule, hospitals would have 15 business days from the date of public display of the FY 2021 IPPS/LTCH PPS final rule to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. We stated that any changes to Factor 3 would be posted on the CMS website prior to October 1, 2020. We acknowledged that this is less time compared to previous years. However, we noted that there is only a limited amount of time for CMS to review the information submitted by the hospitals and to implement the finalized policies before the start of the Federal fiscal year. We explained our belief that hospitals would have sufficient opportunity during the comment period for the proposed rule to provide information about recent and/or pending mergers and/or to report upload discrepancies. We further explained that we expected to use data from the March 2020 HCRIS extract for the FY 2021 final rule, which contributed to our increased confidence that hospitals would be able to comment on mergers and report any upload discrepancies during the comment period following the final rule. However, we also noted that we might consider using more recent data that may become available after March 2020, but before the final rule for purpose of

calculating the final Factor 3s for purposes of the FY 2021 IPPS/LTCH PPS final rule. We stated that in the event that there are any remaining merger updates and/or upload discrepancies after the final rule, the 15 business days from the date of public display of the FY 2021 IPPS/LTCH PPS final rule deadline should allow for the time necessary to prepare and make any corrections to Factor 3 calculations before the beginning of the Federal fiscal year. In addition, we noted that we intend to revisit in future rulemaking whether to discontinue this additional comment process after the final rule, because we believe, in general, the comment period for the proposed rule should provide sufficient opportunity for hospitals to notify CMS regarding pending mergers and/or to report upload discrepancies.

Comment: Several commenters expressed concern related to the proposed 15-business day deadline to submit comments on the accuracy of the supplemental data files after the FY 2021 IPPS/LTCH final rule is posted. A few commenters requested at least 30 days to review the files in order to ensure the accuracy of the data. A commenter indicated that the additional time to review would be especially important in light of the COVID–19 PHE. The commenter also argued that CMS has consistently delayed the release of the proposed rules and that the 15-business day period allocated for review after the final rule is not sufficient. Related to this, a commenter requested that CMS release the proposed rule for FY 2022 and subsequent proposed rules earlier.

A commenter also recommended that CMS provide at least a 14-day period for hospitals to submit corrections to their uncompensated care data arising from MAC and/or CMS mishandling of cost report data either related to a Worksheet S–10 audit and/or any other report upload issue, adding that such a policy would be conceptually consistent with the 14-day period to submit corrections in the merger listing.

Response: We thank the commenters for providing feedback on our proposed 15-business day timeframe to review and submit comments regarding the public use files published in conjunction with this FY 2021 IPPS/LTCH final rule. We are finalizing the proposal as we continue to believe a 15-business day review period is sufficient. Hospitals do not enter into mergers without advanced planning. A hospital can inform CMS during the comment period regarding merger activity not reflected in supplemental file published in conjunction with the proposed rule. This is true irrespective of a PHE. We note also that the historical FY 2017 cost reports are publically available on a quarterly basis on the CMS website for analysis and review of cost report data, which is another opportunity to review cost report data, separate from the supplemental data file published with this final rule.

In regard to the comment requesting a 14-day period to address MAC and/or CMS mishandling of data, we note that we are finalizing our proposal to afford hospitals 15 business days from the public display of the FY 2021 IPPS/LTCH PPS final rule to submit comments on the accuracy of the supplemental data file, including with respect to mergers and/or report upload discrepancies. As noted in the FY 2021 IPPS/LTCH PPS proposed rule, the CMS inbox is not intended for Worksheet S–10 audit process related emails or inquiries, which should be directed to the respective MAC.

As noted in the FY 2021 IPPS/LTCH PPS proposed rule, we intend to revisit the necessity of this additional review period following the publication of the final rule. As discussed in the proposed rule, under usual circumstances the 60-day comment period on the supplemental data file issued with the proposed rule should be sufficient time to provide information about mergers and/or to report upload discrepancies. We note that the December HCRIS extract is usually available in January; thus, stakeholders would be able to perform initial review of that data when it becomes available to confirm their report was properly processed. Therefore, this review could occur before the comment period for the proposed rule. We will take commenters' suggestions into consideration as part of any future rulemaking on the issue of whether a review period following the final rule continues to be needed.

Comment: A commenter identified a discrepancy in the FY 2021 proposed rule's supplemental tables, in which a provider was misclassified as a ''new hospital'' despite having received prior DSH payments. The commenter encouraged CMS to reevaluate the status of the misclassified provider and update the hospital's status accordingly in the public use files in the final rule.

Another commenter pointed out that in the FY 2021 proposed rule's supplemental data file, their hospital is projected to be ineligible for DSH because the data used in the proposed rule was based on a cost reporting year pre-Medicaid expansion. The commenter indicated that while Medicare allows providers to retrospectively settle DSH and uncompensated care payments on their Medicare Cost Reports, MA plans currently do not, resulting in a significant under-reimbursement in FY 2021. According to the commenter, they can only receive DSH payments from MA plans if the uncompensated care rate is loaded into their specific IPPS Pricer File. The commenter requested that CMS consider updating their DSH data to reflect the As Filed 2019 Medicare cost report in the FY 2021 final rule public use file.

Response: We appreciate the commenters' diligence in checking that their own reports and data were properly processed. As appropriate, we have accounted for the inaccuracies identified by commenters in the development of the final rule's DSH supplemental data file published in conjunction with this FY 2021 IPPS/LTCH final rule, and we will continue to pay diligent attention to any data issues and work internally and with our contractors to resolve these issues in a timely manner.

In regard to the commenter's concern about the retrospective settlement of DSH uncompensated care payments on their cost report and the impact of any potential delay in establishing their interim DSH eligibility in relation to their contractual relationship with MA plans, we note that this issue is beyond the scope of this rulemaking.

H. Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs (§ 412.113)

1. Background

Medicare reimburses allogeneic hematopoietic stem cell transplants provided to Medicare beneficiaries for the treatment of certain diagnoses if such treatment is considered reasonable and necessary. Allogeneic hematopoietic stem cell transplants involve collecting or acquiring stem cells from a healthy donor's bone marrow, peripheral blood, or cord blood for intravenous infusion to the recipient. Currently, acquisition costs associated with allogeneic hematopoietic stem cell transplants are included in the operating costs of inpatient hospital services for subsection (d) hospitals (that is, hospitals paid under the IPPS). In addition, IPPS payments for acquisition services associated with allogeneic hematopoietic stem cell transplants are currently included in the MS–DRG payments for the allogeneic hematopoietic stem cell transplants when the transplants occurred in the inpatient setting.

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94; hereafter, ''section 108''), provides that, effective for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant are not included in the definition of ''operating costs of inpatient hospital services'' at section 1886(a)(4) of the Act. In addition, section 108 provides that in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and that the Secretary shall specify the items included in such hematopoietic stem cell acquisition in rulemaking. Section 108 also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner. We discuss each of the amendments under section 108 and our codification and implementation of those amendments, in the sections that follow.

2. Revisions to the Regulations for the Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

a. Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs on a Reasonable Cost Basis

Section 108 amended section 1886(d)(5) of the Act by adding a new paragraph (M)(i) which requires that, for cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual during such a period, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis. In the proposed rule, we proposed to amend 42 CFR 412.113 to reflect this new statutory requirement by adding a new paragraph (e). We proposed that this new paragraph (e) would state that for cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, Medicare payment to such hospital for hematopoietic stem cell acquisition costs is made on a reasonable cost basis. We stated in the proposed rule that this is the same way hospitals with approved transplant centers are reimbursed for their acquisition costs for solid organs under 42 CFR 412.113(d).

In the proposed rule, we proposed to add new paragraph (e)(3) to 42 CFR 412.113 to specify that a subsection (d) hospital that furnishes allogeneic hematopoietic stem cell transplants be required to formulate a standard acquisition charge. We stated in the proposed rule that the hospital's standard acquisition charge is based on costs expected to be reasonably and necessarily incurred in the acquisition of hematopoietic stem cells. In the proposed rule we stated that the standard acquisition charge does not represent the cost of acquiring stem cells for an *individual* allogeneic hematopoietic stem cell transplant; rather, it is a charge that approximates the hospital's average cost of acquiring hematopoietic stem cells for *all* of its allogeneic hematopoietic stem cell transplants. We proposed that the standard acquisition charge would be billed and paid on an interim payment basis as a ''pass-through'' item in accordance with 42 CFR 413.60 and 413.64. We proposed that the actual charges by ancillary cost center from the provider's records would be included on the Medicare cost report and converted to reasonable cost using the corresponding ancillary cost-to-charge ratios. In the proposed rule we also stated that at the end of the cost reporting period, a settlement determination would be made of the actual cost incurred compared to the interim payments made during the period.

We proposed to add new paragraph (e)(5) to 42 CFR 412.113 to specify that a subsection (d) hospital maintain an itemized statement that identifies the services furnished in collecting hematopoietic stem cells, the charges, the person receiving the service (donor/recipient, if donor the provider must identify the prospective recipient), and the recipient's health care insurance number.

We proposed to add new paragraph (e)(4) to 42 CFR 412.113 to specify that the hospital's Medicare share of the hematopoietic stem cell acquisition costs is based on the ratio of the number of its allogeneic hematopoietic stem cell transplants furnished to Medicare beneficiaries to the total number of its allogeneic hematopoietic stem cell transplants furnished to all patients, regardless of payer, applied to reasonable cost. We stated in the proposed rule that this is the same methodology used to reimburse transplant hospitals with approved transplant programs for their acquisition costs for solid organs, and will be further discussed in a forthcoming Paperwork Reduction Act (PRA) package as referenced in section IV.H.3. of the preamble of the proposed rule and this final rule.

In addition, we proposed to amend 42 CFR 412.1(a) to reflect the new statutory requirement by revising the parenthetical identifying other costs related to inpatient hospital services that are paid for on a reasonable cost basis to include costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant. In addition, we proposed to make formatting changes to 42 CFR 412.1(a) to improve the readability of this paragraph. We also proposed to add new paragraph (e)(6) to 42 CFR 412.2 to add the costs of hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant to the list of services which are paid for on a reasonable cost basis.

We summarize in this section the comments we received on these proposals.

Comment: Some commenters supported our proposed amendment to codify the statutory requirements of section 108 which provides for Medicare payment to a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, so that such Medicare payment for allogeneic hematopoietic stem cell costs is made on a reasonable cost basis, effective for cost reporting periods beginning on or after October 1, 2020. A few commenters appreciated our reflecting the timing of this statutory change in the regulation.

Response: We thank the commenters for their support. After consideration of the public comments we received, we are finalizing our proposed changes to 42 CFR 412.1(a) and 412.2 without modification. We are also finalizing our proposal to amend 42 CFR 412.113 by adding a new paragraph (e) to reflect this new statutory requirement, with the modifications described later this section.

Comment: The majority of commenters disagreed with our proposal to require a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to formulate a standard acquisition charge (SAC), as reflected in proposed new paragraph 42 CFR 412.113(e)(3).

A few commenters acknowledged that the proposed billing methodology was the same methodology used for billing solid organ acquisition. However, a commenter noted that because obtaining solid organs frequently involves the use of an Organ Procurement Organization

(OPO) and acquiring stem cells does not, the billing process is not analogous. Many commenters suggested that if the proposed requirement is finalized, a subsection (d) hospital furnishing an allogeneic hematopoietic stem cell transplant would be required to apply the SAC across all payers (for example, commercial payers, Medicaid, etc.), in addition to Medicare. Some of these commenters referenced the instructions provided in the Provider Reimbursement Manual (PRM) 15–1, chapter 22, section 2202.4, which states in part that, ''Charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient.''

These commenters suggested that the proposed requirement, if finalized, would require a hospital to renegotiate its contracts among all payers, which would be administratively burdensome and potentially impact hospital reimbursement. A few commenters noted that although the proposed methodology requires Medicare to reconcile the SAC with actual charges at the end of the cost reporting period, commercial payers would be impacted by this approach because no settlement opportunity exists for them.

Several commenters stated that resources and costs associated with acquiring hematopoietic stem cells for an allogeneic hematopoietic stem cell transplant vary significantly among the different types of donor search and stem cell acquisition services (for example, related, unrelated, cord blood, haploidentical, etc.). Commenters suggested that we consider requiring providers to formulate multiple SACs based on the different type of donor search and stem cell acquisition as they stated this more accurately aligns different costs with the charges associated with the types of acquisition. A commenter also expressed concern that requiring an average charge is another form of ''cost compression.''

The majority of commenters noted that currently, when a subsection (d) hospital furnished an allogeneic hematopoietic stem cell transplant for a Medicare recipient, the hospital holds all allogeneic hematopoietic stem cell acquisition charges and reports the actual allogeneic hematopoietic stem cell acquisition charges under revenue code 0815 (Allogeneic Stem Cell Acquisition/Donor Services), when the transplant occurs. Some commenters noted that this differs from how commercial contracts are structured. Many commenters requested that we not finalize the proposed requirement and alternatively continue to require a subsection (d) hospital to report its actual stem cell acquisition charges under revenue code 0815 when the transplant occurs, which is the method they are accustomed to. These commenters noted that this approach allows all third-party payers to continue their current billing practices, is the least complicated to implement, and achieves the intent of section 108 which requires reimbursement of hematopoietic stem cell acquisition costs on a reasonable cost basis. A commenter noted that if we adopted a SAC, new condition or value codes recently approved by National Uniform Billing Committee (NUBC) would be affected. This commenter wrote that commercial insurance billing practice would be complicated at best or could not occur at worst if transplant centers are mandated to have one SAC for each transplant recipient. A commenter suggested that we delay the implementation of the SAC policy to allow hospitals adequate time to adopt charging and billing protocols to accommodate this new methodology.

Response: We appreciate the commenters' feedback on our proposal to require a subsection (d) hospital furnishing an allogeneic hematopoietic stem cell transplant to formulate and bill a SAC. Our proposal to implement payment for hematopoietic allogeneic stem cell acquisition costs on a reasonable cost basis was modeled after the methodology used by certified transplant centers and OPOs when acquiring solid organs, as such organs are also paid for on the basis of reasonable cost. In the case of solid organs, a SAC is required in order to account for the costs of solid organs acquired by OPOs. We agree that OPOs are frequently involved in solid organ acquisition and that stem cell acquisition does not involve the use of an OPO and, therefore, billing for stem cell acquisition and solid organs is not analogous. We also appreciate the concerns raised by commenters regarding the use of an average charge such as a SAC where there is significant variation in acquisition costs based on the type of donor, and agree that the current methodology of billing actual charges would address these concerns, including ''cost compression'' concerns, and provide more accuracy, given the variability in cost by donor source. While we agree that billing multiple SACs by donor search and acquisition type, as suggested by some commenters, would address concerns about cost variation by donor type better than billing a single SAC, billing multiple SACs would increase complexity and would still be less accurate than billing actual charges. The current methodology for billing allogeneic hematopoietic stem cell acquisition costs is familiar to providers and therefore would be less burdensome for providers, as compared to billing a SAC (or multiple SACs). As commenters noted, it would also appropriately implement the requirement in section 108 that we pay reasonable costs for allogeneic hematopoietic stem cell acquisition. We also believe the continued use of providers' current methodology for billing allogeneic hematopoietic stem cell acquisition charges, in place of formulating and billing a SAC, would address the concerns raised by commenters regarding potential implications for their commercial contracts.

In summary, after consideration of the comments received and for the reasons discussed, we are not finalizing our proposal that subsection (d) hospitals formulate and bill a SAC for allogeneic hematopoietic stem cell acquisition costs. Instead, we are codifying providers' current methodology for billing actual hematopoietic stem cell acquisition charges; that is, that subsection (d) hospitals must continue to hold their actual donor search and hematopoietic stem cell acquisition charges and include them on the Medicare recipient's transplant claim under revenue code 0815. The use of revenue code 0815, as discussed in the hospital OPPS Final Rule, 81 FR 79585–79587, ''should include all services required to acquire stem cells from a donor, as previously defined, and should be reported on the same date of service as the transplant procedure in order to be appropriately packaged for payment purposes.'' Furthermore, the use of revenue code 0815 was requested by CMS and approved by the NUBC, effective January 1, 2017. For the reasons discussed, we believe this final policy is the least burdensome for providers, is familiar to providers, is the most accurate way of billing charges incurred by a subsection (d) hospital for acquiring allogeneic hematopoietic stem cells for an allogeneic hematopoietic stem cell transplant, and appropriately implements section 108. As such, there is no need for a delayed implementation since providers will not need to adapt their charging and billing protocols to accommodate a new methodology.

Therefore, consistent with this final policy, we are codifying under new paragraph (e)(3) of 42 CFR 412.113, that a subsection (d) hospital that furnishes

inpatient allogeneic hematopoietic stem cell transplants is required to hold all allogeneic hematopoietic stem cell acquisition charges and bill them to Medicare using the appropriate revenue code, when the transplant occurs.

Comment: Several commenters stated that our proposal to bill and pay a SAC on an interim payment basis as a ''pass-through'' item would be problematic because of inconsistent use of cost center 77 on the cost reports and a lack of prior years' actual charges by ancillary cost center. Several commenters expressed that until CMS has complete data from cost center 77 and prior years' actual charges by ancillary cost center, the agency must use alternative methods for interim payments for at least the first few years after section 108 is implemented.

These commenters made several recommendations for a temporary methodology to use until cost report data issues are resolved, including providing interim payments to transplant centers using a Provider Statistical and Reimbursement Report summary (PS&R) method, whereby we could use each transplant center's prior year PS&R report's total Medicare charges billed under revenue code 0815, multiply those charges by the individual hospital's cost-to-charge ratio (CCR) and then divide by 26 to develop the initial bi-weekly interim payment amount. Commenters noted that the contractors could update this amount throughout the fiscal year as appropriate, to minimize the amount receivable or payable at cost settlement. Commenters also stated that this option aligns more closely with the way in which CMS handles pass-through payments for solid organs, results in more consistent cash flow for transplant centers, and is familiar to hospital reimbursement staff and to contractors conducting audits.

Alternatively, commenters suggested a claim-based approach using the actual billed charges reported under revenue code 0815 from each submitted transplant recipient's claim multiplied by the hospital's CCR. CMS would then pay this amount on the remittance as a pass-through payment amount in addition to the MS–DRG 014 payment. Commenters noted that this would likely result in a lower incidence of large receivables or payables at cost report settlement as long as CMS allows actual donor charges to be billed. A commenter added that this may better reflect the volume and type of donor/cell acquisition costs involved in hematopoietic stem cell transplants throughout the year.

A few commenters noted that several transplant centers were queried about their preferences, and that either option was acceptable to them; some commenters wrote that both options align with the proposed budget neutrality adjustment in section IV.H.4 of this final rule.

Response: We appreciate the commenters' suggestions. We proposed to make payments on an interim basis as a ''pass-through'' item in accordance with 42 CFR 413.60 and 413.64, which is similar to the way we pay for direct graduate medical education, bad debt and organ acquisition costs. As specified in 42 CFR 413.64(c), before complete cost report data are available, the initial interim rate of payment must be determined by other methods, including allowing the contractor to compute an appropriate interim payment for the initial period using prior year financial data. We acknowledge commenters' concerns with using cost report data, specifically with the inconsistent use of cost center 77, and agree that the agency should use alternative methods for establishing the initial interim payments as described in 42 CFR 413.64(c). We considered commenters' suggestions that the initial interim payment amount should be based upon their Medicare charges reported on their PS&R and billed under revenue code 0815, or upon a claims-based approach.

We agree with commenters who suggested that the initial interim payment amount should be based upon their Medicare charges reported on their PS&R for the cost reporting year that immediately precedes the cost reporting period beginning on or after October 1, 2020 and billed under revenue code 0815. These charges should be multiplied by the individual hospital's CCR to arrive at cost, and then divided by 26 to develop the initial bi-weekly interim payment amount. Interim payments after the initial reporting period will follow 42 CFR 413.64(e). The PS&R methodology allows for more consistent cash flow for hospitals, and is familiar to some hospitals as it is similar to the way CMS handles pass-through payments for direct GME, bad debt, and organ acquisition costs. Therefore, we are finalizing our proposal to provide interim payments on a pass-through basis with the clarification that for the initial period, that is, for the hospital's first cost reporting period beginning on or after October 1, 2020, the initial interim ''pass-through'' payment amount is calculated in accordance with 42 CFR 413.64(c)(3) using each subsection (d) hospital's prior year PS&R report's total Medicare charges billed under revenue code 0815, multiplied by the individual hospital's overall CCR to determine total estimated cost, divided by 26. As already specified in 42 CFR 413.64(c)(4), after the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the contractor that costs have increased. Likewise, the contractor may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate. We note that since providers set their own cost reporting period dates, these initial interim payments will begin at different times during FY 2021, depending on each hospital's cost reporting period.

The regulations at 42 CFR 413.64(e) specify how interim payments are made after the initial period. In accordance with 42 CFR 413.64(e), interim rates of payment made after the initial period for services will be established on the basis of the cost report filed for the previous year covering Medicare services. Therefore, for the cost reporting periods after the initial period, we are clarifying that interim payments will be determined using the cost report filed for the initial period and each subsequent period. The cost report will contain the actual charges by ancillary cost center billed in aggregate under revenue code 0815 and converted to reasonable cost using the corresponding ancillary cost-to-charge ratios. The total of these ancillary costs would be divided by 26 to determine the subsequent biweekly interim payment amounts.

Similar to what occurs with the interim payment for the initial period, this interim rate of payment may be adjusted by the contractor during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the contractor may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

We are also finalizing our proposal that at the end of the cost reporting period, a settlement determination would be made of the actual cost incurred compared to the interim payments made during the period.

Comment: A commenter requested that CMS consider the impact of the ''transitional period,'' where some hospitals will be receiving the reasonable cost-based payment while other hospitals will not, based on the start of hospitals' cost reporting periods. The commenter noted that since the changes to payment for hematopoietic stem cell transplant are effective based

on hospitals' cost reporting periods beginning on or after October 1, 2020, some hospitals may ''benefit'' from the proposed change while others get ''underpaid'' based on when their cost reports are filed, and recommended that we adopt an interim reimbursement mechanism for hospitals from October 1, 2020 until their first cost reports are filed.

Response: Section 108 of Public Law 116–94 specifies that the reasonable cost-based payment for hematopoietic stem cell acquisition costs is effective for cost reporting periods beginning on or after October 1, 2020. While we agree that under this statute providers will begin receiving cost-based payment for hematopoietic stem cell acquisition costs at different times, this is consequence of the statutory language. Providers will continue to be paid as they are currently based on MS–DRG payments until the beginning of a provider's cost reporting period that starts on or after October 1, 2020. Accordingly, we do not believe there is a need for an interim reimbursement mechanism for this limited period.

Comment: A few commenters noted that many itemized statements may be maintained for a single recipient, as there may be several evaluations and work-ups of potential donors before a match is identified. These commenters stated that this results in multiple itemized statements about various donor services to evaluate, collect, and obtain cells for a transplant recipient. Some of these commenters suggested that for clarity, we finalize the following language: Providers must maintain records for all costs defined at 42 CFR 412.113(e)(1) to include all invoices/statements for purchased services and each itemized patient accounting statement for all donors and their service charges. Records must be for the person receiving the service (donor/recipient, if anonymous donor, the provider must identify the prospective recipient), and the recipient's Medicare beneficiary identification number.

Response: We appreciate the commenters' feedback, and agree that the regulation text should reflect that there may be multiple invoices or billing statements for acquisition costs included in the itemized statement in the record for a single recipient. We do not agree with the addition to the regulation text regarding anonymous donors (such as when cord blood is used as the source of the stem cells), as we believe the word ''donor'' covers both anonymous and identified donors. We are modifying the proposed regulation text to make clear that all donor records (anonymous or not) should identify the prospective recipient. We are finalizing that a subsection (d) hospital must maintain an itemized statement that identifies, for all costs defined at 42 CFR 412.113(e)(2), the services furnished in collecting hematopoietic stem cells including all invoices or statements for purchased services for all donors and their service charges. Records must be for the person receiving the services (donor or recipient; for all donor sources, the hospital must identify the prospective recipient), and the recipient's Medicare beneficiary identification number. We note that we are finalizing this regulation at 42 CFR 412.113(e)(4) rather than in 42 CFR 412.113(e)(5) as proposed, because we are not finalizing the proposed text originally in 42 CFR 412.113(e)(4) as discussed in the following comment and response.

Comment: A commenter supported our proposed calculation to determine a hospital's Medicare share of its hematopoietic stem cell acquisition costs, which is based on the ratio of the number of its allogeneic hematopoietic stem cell transplants furnished to Medicare beneficiaries to the total number of its allogeneic hematopoietic stem cell transplants furnished to all patients, regardless of payer, applied to reasonable cost. A few other commenters suggested that this simple ratio may not be sufficiently accurate, and recommended that we convene a panel of hematologists and others with expertise in allogeneic hematopoietic stem cell transplantation to vet this allocation mechanism, and develop a more accurate one if necessary. A commenter requested that we consider clearly defining in regulation and/or policy when allogeneic hematopoietic stem cells should be counted as being used for research and excluded from any acquisition count used to determine the Medicare share of the allowable acquisition cost.

Response: We thank the commenters for their comments. However, since we are not finalizing our proposal that hospitals bill a SAC, but instead are finalizing that hospitals must continue to bill their actual charges for Medicare allogeneic hematopoietic stem cell acquisition as described earlier in this section, there is no need to calculate a Medicare share of the costs; we will be able to directly calculate the actual Medicare costs. Additionally, because the transplant recipient's hospital only bills Medicare once a transplant has occurred, we would not need or have visibility to the cost of allogeneic hematopoietic stem cell acquisitions used for research. For all of these reasons, we are not finalizing the proposed regulation text at 42 CFR 412.113(e)(4) related to calculating the Medicare share of allogeneic hematopoietic stem cell acquisition costs.

b. Definition of Allogeneic Hematopoietic Stem Cell Transplant

We noted in the proposed rule that section 108 amended section 1886(d)(5) of the Act by adding a new paragraph (M)(ii) which defines the term 'allogeneic hematopoietic stem cell transplant' to mean, with respect to an individual, the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect. In the proposed rule, we proposed to codify this definition by adding new paragraph (e)(1) to 42 CFR 412.113.

Comment: Commenters supported our proposed definition of the term 'allogeneic hematopoietic stem cell transplant' made in accordance with Section 108, and our proposed codification of this definition in new paragraph (e)(1) of 42 CFR 412.113.

Response: We appreciate the commenters' support of the proposed definition and we are finalizing our proposal as proposed, without modification.

c. Items Included as Allogeneic Hematopoietic Stem Cell Acquisition Costs

As noted in the proposed rule, section 108 amended section 1886(d)(5) of the Act by adding a new paragraph (M)(i), which also requires that the Secretary specify the items included as allogeneic hematopoietic stem cell acquisition costs through rulemaking. We stated in the proposed rule that allogeneic hematopoietic stem cell acquisition costs apply only to hematopoietic allogeneic stem cell transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). In the proposed rule, specifically, we proposed that allogeneic hematopoietic stem cell acquisition costs would include registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor; tissue typing of donor and recipient; donor evaluation; physician pre-admission/pre-procedure donor evaluation services; costs associated with the collection procedure such as, general routine and special care

services, procedure/operating room and other ancillary services, and apheresis services; post-operative/post-procedure evaluation of donor; and the preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells). We also proposed to codify this definition of allogeneic hematopoietic stem cell acquisition costs by adding proposed new paragraph (e)(2) to 42 CFR 412.113. In the proposed rule, we invited public comments on whether any additional items should be included in the final rule.

Comment: Several commenters supported our proposed items included as allogeneic hematopoietic stem cell acquisition costs. Another commenter expressed support for this proposal because it aligns with the costs hospitals currently incur for hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant. A commenter questioned if transportation of the stem cells should be included as an allowable hematopoietic stem cell acquisition cost and whether a limit on donor follow-up visits should be specified.

Response: We thank the commenters for their support and input. In the proposed rule, we did not propose a limit on donor follow-up visits because a physician determines the medically necessary care that is appropriate and directly and immediately attributable to stem cell donation.

We appreciate the commenter's suggestion regarding transportation costs of allogeneic hematopoietic stem cells and agree that such costs should be included as stem cell acquisition costs when incurred or paid by the recipient hospital and that section 108 provides the authority to include such costs. Therefore, after consideration of the comments received, we are finalizing the proposed list of allogeneic hematopoietic stem cell acquisition costs with modification, to also include transportation costs of stem cells if the recipient hospital incurred or paid such costs. Specifically, we are codifying at new paragraph (e)(2) of 42 CFR 412.113, that allogeneic hematopoietic stem cell acquisition costs would include registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor; tissue typing of donor and recipient; donor evaluation; physician pre-admission/pre-procedure donor evaluation services; costs associated with the collection procedure such as, general routine and special care services, procedure/operating room and other ancillary services, apheresis services and transportation costs of stem cells if the recipient hospital incurred or paid such costs; post-operative/post-procedure evaluation of donor; and the preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

3. Clarification of Hospital Cost Reporting Instructions

In the proposed rule we noted that, in the CY 2017 Outpatient Prospective Payment System (OPPS) final rule (81 FR 79587), we finalized the policy to update the Medicare hospital cost report (Form CMS–2552–10, OMB control number 0938–0050, expiration date March 31, 2022) by adding a new standard cost center, line 77 ''Allogeneic Stem Cell Acquisition'' to Worksheet A (and applicable worksheets) with the standard cost center code of ''07700.'' The new cost center line was established to record any acquisition costs related to allogeneic stem cell transplants as defined in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100–04) in order to develop an accurate estimate of allogeneic hematopoietic stem cell donor acquisition costs for future ratesetting. In the proposed rule, we noted there is a similar discussion of allogeneic stem cell acquisition costs when the transplant occurs in the inpatient setting found in the Medicare Claims Processing Manual (Pub 100–04), Chapter 3, Section 90.3.1. We stated in the proposed rule that with the establishment of this line came additional challenges on how to reclassify expenses into the new cost center from routine and ancillary departments. In addition, we stated in the proposed rule that we found inconsistencies in the reporting of costs and charges for allogeneic hematopoietic stem cell acquisition costs.

In the proposed rule we noted that the current cost reporting instructions require providers to report on line 77, the acquisition costs for allogeneic stem cell transplants. Line 77 only allows providers to report direct expenses, and does not provide a method for determining other routine and ancillary costs that are part of the allogeneic stem cell acquisition costs. We stated in the proposed rule that some providers are reclassifying costs from routine and ancillary cost centers to line 77. However, as noted in the proposed rule, this practice does not align costs and charges properly in accordance with the Provider Reimbursement Manual, 15–1, chapter 23, sections 2300, 2302.7 and 2302.8 (available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*). In addition, we stated in the proposed rule that in order to reimburse allogeneic hematopoietic stem cell acquisition costs on a reasonable cost basis as required by section 108, and to accommodate the reporting of both direct and indirect costs on line 77 as well as routine and ancillary costs associated with the acquisition of hematopoietic stem cells, we are modifying cost reporting forms and instructions. We also noted in the proposed rule that we are developing a worksheet similar to the Worksheet D–4 for solid organs that will allow providers to capture costs from line 77 as well as to report charges by routine and ancillary cost center and compute the related costs.

In the proposed rule, we stated that changes to the forms and instructions will be described in more detail in a forthcoming PRA package, with comment period. We noted in the proposed rule that the forthcoming PRA package will address providers' requests for a standardized format for data collection as referenced in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41681 through 41684) and Worksheet S–10 modifications as referenced in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42375).

Comment: Several commenters agreed that the current cost reporting forms and instructions require modification in order to facilitate reimbursement of allogeneic hematopoietic stem cell acquisition costs. A few commenters expressed support of our developing a worksheet for stem cell acquisition cost that is similar to the Worksheet D–4, for solid organ acquisition costs. A few commenters agreed that the current forms and instructions do not provide a method for determining other routine and ancillary costs that are part of allogeneic hematopoietic stem cell acquisition, and the lack of instruction has resulted in inconsistencies. Commenters suggested that detailed instructions would benefit providers. A commenter also requested confirmation that both direct and indirect costs should be reported on line 77. Finally, a commenter requested that we consider modifying the Worksheet S–2, Part I, to allow for better cost report editing regarding the use of Worksheet A, cost center 77, and our development of a worksheet similar to Worksheet D–4.

Response: We thank the commenters for their support and input. We appreciate the commenters' concerns regarding the current challenges of

reporting stem cell acquisition costs on line 77. We are considering the commenter's request to modify Worksheet S–2, Part I, to enhance editing and improve compliance with reporting of allogeneic hematopoietic stem cell acquisition costs.

We appreciate that commenters concurred with our developing a worksheet to report allogeneic hematopoietic stem cell acquisition costs similar to the worksheet for solid organs. This new worksheet will allow providers to capture Medicare's share of costs from line 77 as well as to report charges by routine and ancillary cost centers and compute the related costs. As stated in the proposed rule, line 77 only allows providers to report direct expenses, and does not provide a method for determining routine and ancillary costs that are part of the allogeneic stem cell acquisition costs. In addition, our changes will include associated updates and clarifications to the cost reporting instructions. Commenters will have an opportunity to comment on the modifications to the Medicare hospital cost report forms and instructions in a forthcoming PRA package.

Comment: Several commenters suggested we update the sub-regulatory guidance that references allogeneic hematopoietic stem cell transplants. Another commenter questioned why we were proposing to add details regarding allogeneic hematopoietic stem cell acquisition costs to the regulation text, instead of sub-regulatory guidance through CMS policy manuals or cost reporting instructions.

Response: We note that section 108 requires the Secretary to specify in rulemaking the items included in allogeneic hematopoietic stem cell acquisition costs. In addition, modifications will be made to the CMS policy manuals, specifically PRM 15–1, chapter 24, PRM 15–2, chapter 40, and the Medicare Claims Processing Manual (Pub 100–04) chapters 3 and 4.

Comment: A commenter questioned if there is a Medicare certification for allogeneic hematopoietic stem cell transplants that needs to be verified, similar to that for solid organs, and if so, will it be published at a central location.

Response: A subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant is not required to be a Medicare certified transplant center as is required for solid organs; therefore, a hospital that bills using revenue code 0815 for inpatient allogeneic hematopoietic stem cells is sufficient verification.

Comment: A commenter requested that we address how section 108 of the Further Consolidated Appropriations Act, 2020 will affect Medicare Advantage (MA) organizations' payments for allogeneic hematopoietic stem cell acquisition costs in both in-network and out-of-network cases. This same commenter requested that the relevant MA manuals be updated to reflect the section 108 changes in payment for allogeneic hematopoietic stem cell acquisition.

Response: Under section 1852(a) of the Act, when an MA organization's coverage responsibilities include payment for services furnished to an MA enrollee by a hospital with which the MA organization does not have a contract that establishes a payment amount, the MA organization's payment to the hospital must be equal to the total dollar amount that would have been authorized for such services under the Medicare FFS program, less any cost-sharing paid by the enrollee under the MA plan. In addition, section 1866(a)(1)(O) of the Act provides that a hospital that does not have a contract establishing payment amounts for services furnished to an MA enrollee must accept as payment in full the amount that the hospital would be paid if the MA enrollee had instead been enrolled in Medicare FFS. The payment amount established in this rule for the Medicare FFS program would therefore apply in cases where an MA organization must cover allogeneic hematopoietic stem cell acquisition costs when the MA enrollee receives the relevant services from a non-contracted hospital. CMS does not interfere in the contracts between an MA organization and its contracted providers to require either the MA organization to contract with a specific provider or to require a specific payment or pricing arrangement; an MA organization and its contracted providers may negotiate payment arrangements for covered services furnished to MA enrollees. For in-network services and services furnished by contracted providers to MA enrollees, this rule and the amendments to section 1886(d) of the Act by section 108 of the Further Consolidated Appropriations Act, 2020, do not impose or set the payment amount from an MA organization for these services. CMS will consider whether additional guidance specific to payment for allogeneic hematopoietic stem cell acquisition by MA organizations is necessary.

4. Budget Neutrality for the Reasonable Cost Based Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) amended section 1886(d)(4)(C)(iii) of the Act to require that beginning with FY 2021, the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs be made in a manner that assures that the aggregate IPPS payments for discharges in the fiscal year are not greater or less than those that would have been made without such payments; that is, that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs be made in a budget neutral manner.

To implement this requirement, we proposed to make an adjustment to the standardized amount to ensure the effects of the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, as required under section 108 of Public Law 116–94. We also proposed to codify this budget neutrality requirement by adding new paragraph (e)(5) to 412.64 to specify that CMS makes an adjustment to the standardized amount to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are made in a manner so that aggregate payments to hospitals are not affected.

When the allogeneic stem cell transplant occurs in the inpatient setting, the hospital identifies stem cell acquisition charges for allogeneic hematopoietic stem cell transplants separately using revenue code 0815 on the inpatient hospital bill (see Medicare Claims Processing Manual, CMS Pub. 100–04, Chapter 3, section 90.3.1.B., which is available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03pdf.pdf*). To estimate the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for purposes of the budget neutrality adjustment, we used the charges reported on the hospital's inpatient claim in revenue center code 0815 (which is reflected in the MedPAR field for the Revenue Center Allogeneic Stem Cell Acquisition/Donor Services) and converted those charges to costs by applying the hospital's operating CCR (that is, the same hospital-specific CCR used to estimate the hospital's operating outlier payments).

In the proposed rule, based on the latest data at that time (that is, claims

from the December 2019 update of the FY 2019 MedPAR file and CCRs from the December 2019 update of the PSF), we estimated that reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for FY 2021 would be $15,865,373.61. Therefore, the total amount that we proposed to use to make an adjustment to the standardized amounts to ensure the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral was $15,865,373.61. We further proposed that if more recent data become available for the final rule, we would use that data to determine the final amount we would use to make the budget neutrality adjustment. (We refer readers to section II.A.4.f. of the Addendum of the proposed rule for discussion of the budget neutrality adjustment factor we proposed to apply to the standardized amounts for FY 2021 based on these estimated allogeneic hematopoietic stem cell acquisition costs.)

Comment: We received comments supporting our proposed approach for estimating the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for FY 2021 for purposes of the budget neutrality requirement of section 108 of Public Law 116–94.

Response: We appreciate the commenters' support for our proposed approach.

After consideration of public comments, we are finalizing our proposed approach for estimating the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for FY 2021 for purposes of the budget neutrality requirement of section 108 of Public Law 116–94 without modification, as well as our proposed codification of this budget neutrality requirement at new paragraph § 412.64(e)(5). Consistent with our proposal to use more recent available data for this final rule (claims from the March 2020 update of the FY 2019 MedPAR file and CCRs from the March 2020 update of the PSF), we estimate that reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for FY 2021 will be $16,167,790.60. Therefore, the total amount that we are using to make an adjustment to the standardized amounts to ensure the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral is $16,167,790.60. (We refer readers to section II.A.4.f. of the Addendum of this final rule for discussion of the budget neutrality adjustment factor we are applying to the standardized amounts for FY 2021 based on these estimated allogeneic hematopoietic stem cell acquisition costs.)

I. Payment Adjustment for CAR T-Cell Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

As discussed in section II.D.2.b. of the preamble of this final rule, we proposed, and are finalizing, the creation of new MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which are currently reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. As a requestor noted, a large percentage of the total cases that would group to any new MS–DRG for CAR T-cell therapy cases would be clinical trial cases, in which the provider typically does not incur the cost of the drug. By comparison, for non-clinical trial cases involving CAR T-cell therapy, the drug cost is an extremely large portion of the total costs. To address this, as described in section II.E.2.b. of this final rule, we proposed to modify our relative weight methodology for new MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, in determining the relative weights, we proposed that clinical trial claims, that group to new MS–DRG 018 would not be included when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight generally reflects the costs of the CAR T-cell therapy drug. We refer readers to section II.E.2.b. of this final rule for discussion of our finalized modifications to our relative weight methodology relating to clinical trial cases involving CAR–T cell therapy.

Cases involving clinical trials, like non-clinical trial cases, are currently paid using the same relative weight for the MS–DRG to which the case is assigned. However, given that the drug cost is an extremely large portion of the total costs of the non-clinical trial CAR T-cell therapy cases, and that the relative weight for new MS–DRG 018 assumes that the provider has incurred the costs of the CAR T-cell therapy drug, we proposed an adjustment to the payment amount for clinical trial cases that would group to new MS–DRG 018. We proposed to calculate this adjustment using the same methodology that we proposed to use to adjust the case count for purposes of the relative weight calculations:

- Calculate the average cost for cases to be assigned to new MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to new MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

Consistent with our methodology for calculating the proposed case count adjustment for purposes of the relative weight calculations, for FY 2021, for purposes of calculating this proposed payment adjustment, we identified clinical trial claims to be those historical claims that contain ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) or contain the proxy of standardized drug charges of less than $373,000.

For FY 2021, based on the claims data from the December 2019 update of the FY 2019 MedPAR files used for the proposed rule, the ratio of the average cost for CAR T-cell therapy cases identified as clinical trial cases to the average cost for non-clinical trial CAR T-cell therapy cases (that is, those cases not identified as being clinical trial cases) was 0.15. Therefore, we proposed that the adjustor that would be applied to CAR T-cell therapy clinical trial claims would be 0.15. For example, if the relative weight for new MS–DRG 018 was 30.00, we proposed we would multiply 30.00 by the adjustor of 0.15 as part of the calculation of the payment for clinical trial claims assigned to new MS–DRG 018.

We stated in the proposed rule that the claims involving CAR T-cell therapy that would be subject to this proposed adjustment would be cases that would group to new MS–DRG 18 and include ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program). ICD–10–CM diagnosis code Z00.6 is required to be included with clinical trial cases and we stated that we expect hospitals to include this code for clinical trial cases that would group to MS–DRG 18 for FY 2021 and all subsequent years. Consistent with our historical practice, we also proposed to update the value of the adjustor based on more recent data for the final rule.

We also proposed to amend our regulations at 42 CFR part 412, subpart F (for operating IPPS payments), and 42

CFR 412.312 (for capital IPPS payments) to codify this proposed payment adjustment for certain clinical trial cases. Under 42 CFR part 412, subpart F, we proposed to redesignate existing § 412.86 (which sets forth payment for extraordinarily high-cost day outliers for discharges occurring before October 1, 1997) as new § 412.83, and to add a new center heading and new § 412.85 to codify the proposed payment adjustment for certain clinical trial cases. We also proposed to make conforming changes to § 412.82(c) to replace the reference to § 412.86 with § 412.83, and proposed to reserve § 412.86. We proposed this restructuring to subpart F in order to keep the sections related to payment for outlier cases together under the ''Payment for Outlier Cases'' center heading when adding the proposed section to codify the proposed payment adjustment. Specifically, proposed new § 412.85 provides for a payment adjustment for a discharge assigned to MS–DRG 018 that is part of a clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge. Proposed new § 412.85 further provides that payment for such a discharge is adjusted by adjusting the DRG weighting factor determined under § 412.60(b) by a factor that reflects the average cost for cases to be assigned to MS–DRG 018 that are part of a clinical trial to the average cost for cases to be assigned to MS–DRG 018 that are not part of a clinical trial. Similarly, we proposed to add paragraph (f) to § 412.312 to specify that in determining the capital IPPS payments under that section for certain clinical trial cases as described in § 412.85(b), the DRG weighting factor described in § 412.312(b)(1) is adjusted as described in § 412.85(c).

Comment: Several commenters expressed concerns about the potential for over and under-payments due to CMS' proposed methodology for defining clinical trial claims as those that group to new MS–DRG 18 and include ICD–10–CM diagnosis code Z00.6. Commenters stated that when CAR T-cell therapy products are used out of specification (also termed expanded access), hospitals do not incur the cost of the CAR T-cell therapy product, but the claim would not include ICD–10–CM diagnosis code Z00.6 because the case is not part of a clinical trial. Commenters identified an additional scenario, in which the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of another drug, in which case ICD–10–CM diagnosis code Z00.6 would be included on the claim. A commenter requested that CMS clarify that ICD–10–CM diagnosis code Z00.6 may be reported in this instance. Other commenters requested that CMS require hospitals to report their acquisition cost in value code 90, which could then be used to identify whether the provider incurred the cost of the CAR T-cell therapy product. A commenter stated that the administrative burden to hospitals to report their acquisition costs would be outweighed by the value of the data collected to improve future rulemaking. Another commenter recommended that CMS require hospitals to use the NDC codes or cross-reference the clinical trial ID on the claim to determine whether the trial is studying CAR T-cell therapies or one of the drugs treating complications. A commenter requested that CMS monitor the proposed adjustment for clinical trial cases of 0.15 to ensure it is adequate to cover the cost of inpatient care for patients participating in a clinical trial for CAR T-cell therapies.

Response: While we disagree with commenters' characterization of these situations as potential overpayments or underpayments given the nature of the IPPS, we do agree with commenters that given that the product cost is an extremely large portion of the total costs of CAR T-cell therapy cases that do not involve a clinical trial of the CAR T-cell therapy product, and that the relative weight for new MS–DRG 018 assumes that the provider has incurred the costs of the CAR T-cell therapy product, the same adjustment should be applied to payment for cases involving expanded access use of immunotherapy where the hospital does not incur the cost of the CAR T-cell therapy product. For this same reason, as well as mitigating potential disincentives related to clinical trial participation, we also agree with commenters that when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment should not be applied in calculating the payment for the case. We believe the application of this policy to the scenarios identified by the commenters, while occurring with less frequency, is consistent with our proposal to apply a differential payment for cases where the CAR T-cell therapy product is provided without cost to ensure that the payment amount appropriately reflects the relative resources required for such cases.

We will provide instructions for identifying these claims in separate guidance. We may consider refinements to our policy in future rulemaking as we gain more experience with this new adjustment.

After consideration of public comments received, we are finalizing our proposal to apply a payment adjustment to claims that group to new MS–DRG 18 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We are also finalizing a modification to our proposed policy that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case.

We are also finalizing our proposed methodology for calculating this adjustment, which is the same methodology we are finalizing to adjust the case count for purposes of the relative weight calculations, which includes refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. To the best of our knowledge there are no claims in the historical data used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000. We are also finalizing our proposal to update the value of the adjustor based on more recent data for this final rule. As discussed elsewhere in this final rule, based on the claims data from the March 2020 update of the FY 2019 MedPAR files used for this final rule, the ratio of the average cost for CAR T-cell therapy cases determined to be clinical trial or expanded access use immunotherapy cases to the average cost for other CAR T-cell therapy cases (that is, those cases not determined to be clinical trial cases) is 0.17. Therefore, we are finalizing that the adjustor that will be applied to CAR T-cell therapy clinical trial or expanded access use immunotherapy cases for FY 2021 is 0.17. That is, we will multiply the final FY 2021 relative weight for new MS–DRG 018 by the final adjustor of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use

access immunotherapy claims assigned to new MS–DRG 018.

We are also finalizing our proposed amendments to our regulations at 42 CFR part 412, subpart F (for operating IPPS payments), and 42 CFR 412.312 (for capital IPPS payments) to codify this payment adjustment for claims appropriately containing Z00.6, as described previously, with modification to proposed new 42 CFR 412.85(b) and 412.312(f) to reflect that the adjustment will also be applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, as discussed previously, the adjustment is not applicable to cases where the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. We are also finalizing our proposed amendments to 42 CFR 412.85(c) with modification to reflect that the adjustment factor will reflect the average cost for cases to be assigned to MS DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial.

J. Changes for Hospitals With High Percentage of End Stage Renal Disease (ESRD) Discharges (§ 412.104)

Under § 412.104(a), CMS provides an additional payment to a hospital for inpatient services provided to End Stage Renal Disease (ESRD) beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into MS–DRG 652 (Kidney Transplant), MS–DRG 682 (Renal Failure with MCC), MS–DRG 683 (Renal Failure with CC), MS–DRG 684 (Renal Failure without CC/MCC) and MS–DRG 685 (Admit for Renal Dialysis), where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges. (We note that in existing § 412.104(a), the title of MS DRG 652 is mistakenly shown as ''Renal Failure'' instead of ''Kidney Transplant''.)

As explained in the proposed rule (85 FR 32765 through 32766), for FY 2021, we proposed to create a new Pre-MDC MS–DRG for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant (proposed new MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis)). We also proposed to create two new MS–DRGs with a two-way severity level split for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11 (proposed new MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC) and proposed new MS–DRG 651 (Kidney Transplant with Hemodialysis without MCC)). We also explained that the proposed relative weights for these MS–DRGs reflect the resources related to the provision of inpatient hemodialysis, and accordingly, we believe that discharges classified to these new proposed MS–DRGs should be excluded in determining a hospital's eligibility for the additional payment for hospitals with high percentages of ESRD discharges. Therefore, we proposed to add MS–DRGs 019, 650, and 651 to the list of excluded MS–DRGs set forth in § 412.104(a). We further explained that under the proposed MS–DRG logic for kidney transplants, a case with a hemodialysis procedure reported on the claim would no longer group to MS–DRG 652 (Kidney Transplant). (We note, as discussed in section II.D.8.a. of the preamble of this final rule, that we are finalizing the creation of new MS–DRGs 019, 650 and 651, and the related MS–DRG logic for kidney transplants.) We also noted that MS–DRG 685 (Admit for Renal Dialysis) was deleted effective FY 2019 (83 FR 41201 through 41202). Therefore, we proposed to remove MS–DRGs 652 and 685 from the list of excluded MS–DRGs set forth in § 412.104(a).

We proposed to revise § 412.104(a) to reflect these changes to the MS–DRG logic for kidney transplants and the previous deletion of MS–DRG 685. We also proposed to make formatting changes to this provision to list the MS–DRG exclusions.

Comments: A commenter suggested that additions and removals of MS–DRGs from § 412.104(a) should be done based on effective dates.

Response: We do not believe it is necessary to use effective dates in § 412.104(a) for the addition and removal of MS–DRGs from the list of MS–DRGs excluded in the determination of a hospital's eligibility for the additional payment for hospitals with high percentages of ESRD discharges. For example, although MS–DRG 685 was deleted effective FY 2019, its inclusion in the list of excluded MS–DRGs in § 412.104(a) would not have impacted a hospital's ability to qualify for the add-on payment since the hospital would not have had any discharges on or after October 1, 2018 classified into MS–DRG 685.

After consideration of public comments, we are finalizing our proposal without modification. (As previously noted, and as discussed in section II.D.8.a. of the preamble of this final rule, we are finalizing the creation of new MS–DRGs 019, 650 and 651 which describe the performance of hemodialysis in an admission where the patient received a either a simultaneous pancreas/kidney transplant or a kidney transplant.)

K. Hospital Readmissions Reduction Program: Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the proportion of beneficiaries who are dually eligible for Medicare and full-benefit Medicaid (dual-eligibles) in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676).
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676).
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048).
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543).
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979).
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439).

• FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390).

These rules describe the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of measures for the applicable conditions/procedures; (2) the measure removal factors policy; (3) the calculation of the excess readmission ratio (ERR), which is used, in part, to calculate the payment adjustment factor; (4) the calculation of the proportion of ''dually eligible'' Medicare beneficiaries which is used to stratify hospitals into peer groups and establish the peer group median ERRs; (5) the calculation of the payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions (including calculating the peer group median ERRs), aggregate payments for all discharges, and the neutrality modifier; (6) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare* or its successor; (7) the extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (8) the clarification that the public reporting of ERRs will be posted on an annual basis to the *Hospital Compare* website or its successor as soon as is feasible following the review and corrections period; and (9) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in United States territories and Puerto Rico.

We also have codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154. In section IV.K.11. of the preamble of this final rule, we are updating the regulatory text to reflect the policies that we are finalizing in this final rule.

We note that we received public comments on the effectiveness, measures, and methodology of the Hospital Readmissions Reduction Program in response to the FY 2021 IPPS/LTCH PPS proposed rule. We also received public comments related to the social risk adjustment in the Hospital Readmissions Reduction Program and confidential reporting of stratified data for the six readmission measures. While we appreciate the commenters' feedback, because we did not include any proposals related to these topics in the proposed rule, we consider the public comments to be out of the scope of the proposed rule. However, all topics that we consider to be out of scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years.

3. Summary of Policies for the Hospital Readmissions Reduction Program

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed the automatic adoption of applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary. Additionally, we proposed to update the definition of applicable period at 42 CFR 412.152 to align with this proposal. After consideration of the public comments we received, we are finalizing our policies as proposed. We discuss comments on these policies within the respective sections of this final rule.

4. Current Measures for FY 2021 and Subsequent Years

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Initiative. We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. Therefore, we did not propose to remove or adopt any additional measures at this time.

5. Definition of ''Dual-Eligible'' Beginning in FY 2021 and for Subsequent Years

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38229), as part of implementing the 21st Century Cures Act, we finalized the definition of dual-eligible as follows: ''[A]n individual would be counted as a full-benefit dual patient if the beneficiary was identified as full-benefit dual status in the State [Medicare Modernization Act] (MMA) files for the month he/she was discharged from the hospital.'' In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41437 through 41438), we codified this definition at 42 CFR 412.152 along with other definitions pertinent to dual-eligibility calculations for assigning hospitals into peer groups.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42384 through 42385), we finalized an update to the definition of ''dual-eligible'' to specify that, for the payment adjustment factors beginning with the FY 2021 program year, ''dual-eligible'' is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files.

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42384 through 42385) for a more detailed discussion of this topic. We did not propose any updates to our definition of ''dual-eligible'' beneficiaries in this rule.

6. Automatic Adoption of Applicable Periods for FY 2023 and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53375) for discussion of our previously finalized policy for defining applicable periods. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41434 through 41435) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42387), we finalized the following ''applicable periods'' consistent with the definition specified at 42 CFR 412.152, to calculate the readmission payment adjustment factor for FY 2021 and FY 2022, respectively:

• The 3-year time period of July 1, 2016 through June 30, 2019 for FY 2021.

• The 3-year time period of July 1, 2017 through June 30, 2020 for FY 2022.[434]

This is the 3-year period from which CMS uses claims data to calculate ERRs and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment

[434] In accordance with the August 25th COVID IFC, no claims data reflecting services provided January 1, 2020–June 30, 2020 will be used in calculations for the Hospital Readmissions Reduction Program among other Medicare quality reporting and value-based purchasing programs. Therefore, the FY 2022 Hospital Readmissions Reduction Program will only use data from July 1, 2017 through December 31, 2019 for calculations. For more details see the August 25th COVID IFC.

adjustment. The ''applicable period'' for dual-eligibles is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

In order to provide greater certainty around future applicable periods for the Hospital Readmissions Reduction Program, we proposed the automatic adoption of applicable periods for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program. Beginning in FY 2023, the applicable period for the Hospital Readmissions Reduction Program will be the 3-year period beginning one year advanced from previous program fiscal year's start of the applicable period. That is, for FY 2023, the applicable period for the Hospital Readmissions Reduction Program measures and for determining dual eligibility and payment adjustment factors will be the 3-year period from July 1, 2018 through June 30, 2021, which is advanced one year from the applicable period for the FY 2022 Hospital Readmissions Reduction Program. Under this policy, for all subsequent years, we would advance this 3-year period by one year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. Similarly, the applicable period for dual eligibility will continue to correspond to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. We believe that the automatic adoption of the applicable period each year will streamline the process and provide additional clarity and consistency to the Program. We received several public comments on the proposal for automatic adoption of applicable periods.

Comment: Commenters expressed support for the automatic adoption of applicable periods. Several commenters viewed this proposal as a minimal change and noted that this proposal would provide continuity and consistency for future program years.

Response: We thank the commenters for their support.

After consideration of the public comments that we received, we are finalizing our proposal to automatically adopt applicable periods for the Hospital Readmissions Reduction Program beginning with the FY 2023 program year.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2021

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure, using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2021 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring on or after October 1, 2015 (FY 2016) began reporting under the ICD–10– CM and ICD–10–PCS code sets as opposed to the previous ICD–9CM code set.

We identify Medicare fee-for-service (FFS) claims that meet the criteria previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. This means that claims paid for under Medicare Part C (Medicare Advantage) are not included in this calculation. This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2021, we proposed to continue to exclude admissions for patients enrolled in Medicare Advantage (MA), as identified in the Medicare Enrollment Database.

For FY 2021, we proposed to determine aggregate payments for excess readmissions, and aggregate payments for all discharges using data from MedPAR claims with discharge dates that align with the FY 2021 applicable period. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we will determine the neutrality modifier using the most recently available full year of MedPAR data. However, we note that, for the purpose of modeling the estimated FY 2021 readmissions payment adjustment factors for this final rule, we used the proportion of dual-eligibles, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2021 Hospital Readmissions Reduction Program applicable period. For the FY 2021 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2021 applicable period of July 1, 2016 to June 30, 2019, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and correction process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

We proposed the continued use of the MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations. We proposed to use the March update of the fiscal year MedPAR to identify discharges within the applicable period during that fiscal year. We received no comments on this proposal, and therefore are finalizing our proposal to use MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program without modification.

8. Calculation of Payment Adjustment Factors for FY 2021

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. Section 1886(q)(3)(D) also states that this methodology could be replaced through the application of subclause (E)(i), which states that the Secretary may take into account the studies conducted and the recommendations made by the reports required by section 2(d)(1) of the IMPACT Act of 2014 (Pub. L. 113–185; 42 U.S.C. 1395 note) with respect to risk adjustment methodologies. The second Office of the Assistant Secretary for Planning and Evaluation (ASPE) study on social risk and Medicare's value-based purchasing programs came out on June 29, 2020. We will examine these recommendations more closely going forward.

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. We did not propose any

changes to this payment adjustment calculation methodology for FY 2021.

9. Calculation of Payment Adjustment for FY 2021

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(1) the aggregate payments for excess readmissions; and (2) the aggregate payments for all discharges, scaled by the neutrality modifier. The methodology used for the calculation of this ratio is codified at 42 CFR 412.154(c)(1) and the methodology for the calculation of the floor adjustment factor is codified at 42 CFR 412.154(c)(2). Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at 42 CFR 412.154(c)(2), for FY 2021, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2021, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

For additional information on the FY 2021 payment calculation, we refer readers to the Hospital Readmissions Reduction Program information and resources available on our *QualityNet* website. We did not propose any changes to our calculation of the payment methodology.

10. Confidential Reporting of Stratified Data for Hospital Quality Measures

Consistent with our plans described in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42388 through 42390), we included in confidential hospital-specific reports (HSR) data stratified by patient dual-eligible status for the six readmissions measures included in the Hospital Readmissions Reduction Program in the Spring of 2020. These data included two disparity methodologies designed to illuminate potential disparities within individual hospitals and across hospitals nationally and supplement the measure data currently publicly reported on the *Hospital Compare* website. However, these stratified data are provided in confidential reports and not publicly reported at this time. The first methodology, the Within-Hospital Disparity Method, highlights differences in outcomes for dual-eligible versus non-dual-eligible patients within an individual hospital, while the second methodology, the Dual Eligible Outcome Method, allows for a comparison of performance in care for dual-eligible patients across hospitals (82 FR 38405 through 38407; 83 FR 41598; 84 FR 42388 through 42389). These two disparity methods are separate from the methodology used by the Hospital Readmissions Reduction Program that assesses hospital performance relative to other hospitals with a similar proportion of dual-eligible patients (that is, peer group), and we emphasize that the two disparity methods would not be used in payment adjustment factor calculations under the Hospital Readmissions Reduction Program. We note that the two disparity methods do not place any additional collection or reporting burden on hospitals because dual-eligibility data are readily available in claims data. In addition, we reiterate that these confidential hospital-specific reports data do not impact the calculation of hospital payment adjustment factors under the Hospital Readmissions Reduction Program.

We did not propose any updates to the confidential reporting of stratified data in the proposed rule.

11. Revisions of Regulatory Text

We proposed to revise 42 CFR 412.152 to reflect the proposed policy to automatically adopt applicable periods for the Program as previously discussed in section IV.K.6. of the preamble of this final rule. Specifically, we proposed to revise the definition of ''applicable period'' and ''applicable period for dual eligibility'' as follows:

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program. The applicable period for FY 2022 is the 3-year period from July 1, 2017 through June 30, 2020. Beginning with the FY 2023 program year, the applicable period is the 3-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary.

Applicable period for dual-eligibility is the 3-year data period corresponding to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise established by the Secretary.

We received several public comments on our proposal to revise 42 CFR 412.152 to reflect the proposed policy to automatically adopt applicable periods for the Program.

Comment: Commenters supported this proposal. Several commenters viewed this proposal as a minimal change and noted that this proposal would provide continuity and consistency for future program years.

Response: We thank commenters for their support.

After consideration of the public comments that we received, we are finalizing our proposal to update the regulatory text as proposed.

12. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772 through 49082), we proposed a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital Readmissions Reduction Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC proposed rule for details.

L. Hospital Value-Based Purchasing (VBP) Program: Updates

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act requires the Secretary to establish a hospital value based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule

(78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38240 through 38269); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41472); and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42390 through 42402).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2021 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details.

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2021 program year is 2 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2021 is approximately $1.9 billion, based on the March 2020 update of the FY 2019 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2021, on a per-claim basis. We published proxy value-based incentive payment adjustment factors in Table 16 associated with the FY 2021 IPPS/LTCH PPS proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-proposed-rule-home-page#Tables*). We are publishing updated proxy value-based incentive payment adjustment factors in Table 16A associated with this final rule (available via the internet on the CMS website). The proxy factors are based on the TPSs from the FY 2020 program year. These FY 2020 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The updated slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in Table 16A is 2.8109251372. This slope, along with the estimated amount available for value-based incentive payments, has been updated based on the March 2020 update to the FY 2019 MedPAR file and is also published in Table 16A (available via the internet on the CMS website).

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2021, we will post Table 16B associated with the final rule (which will be available via the internet on the CMS website) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2021 program year. We expect Table 16B will be posted on the CMS website in the Fall of 2020.

2. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (that is, we have selected the measure from the Hospital IQR Program measure set and included data on that measure on *Hospital Compare* or its successor for at least 1 year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP Program statute does not require that the measure continue to remain in the Hospital IQR Program. We did not propose any changes to these policies.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), in alignment with the Hospital IQR Program, we finalized measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. We did not propose any changes to these policies.

c. Summary of Previously Adopted Measures for the FY 2023 and FY 2024 Program Years

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42392 through 42393) for summaries of previously adopted measures for the FY 2022 and FY 2023 program years, and to the tables in this section showing summaries of previously adopted measures for the FY 2023 and FY 2024 program years. We note that in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32769 through 32771), we did not propose to add new measures or remove measures from the Hospital VBP Program.

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Summary of Previously Adopted Measures for the FY 2023 and FY 2024 Program Years		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753

Summary of Previously Adopted Measures for the FY 2023 and FY 2024 Program Years		
Measure Short Name	**Domain/Measure Name**	**NQF #**
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
CMS PSI 90*	CMS Patient Safety and Adverse Events Composite*	0531
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE**	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42392 through 42393), we updated the name of the Patient Safety and Adverse Events Composite (PSI 90) to the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) when it is used in CMS programs due to transition of the measure from AHRQ to CMS.
** We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42392 through 42393), we updated the short name of the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) from THA/TKA to COMP-HIP-KNEE in order to maintain consistency with the updated Measure ID and short name used in tables on *Hospital Compare* and/or its successor and hospital reports for the Hospital VBP Program.

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3. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for baseline and performance periods that we have adopted for the FY 2020, FY 2021, and FY 2022 program years. In the same final rule, we finalized a schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42393 through 42395) for additional baseline and performance periods that we have adopted for the FY 2022, FY 2023, and subsequent program years.

We note that on March 22, 2020,[435] in response to the COVID–19 Public Health Emergency (PHE), we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare QRPs and VBP programs. In addition, on

[435] CMS Announced Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Available at: *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

March 27, 2020,[436] we published a supplemental guidance memorandum that described in more detail the scope and duration of the nationwide ECEs we were granting under each Medicare QRP and VBP program. Due to concerns about the national comparability of the data we updated the nationwide ECE to allow us to not score these data, even if voluntarily reported, in the Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency announced on August 25, 2020 (hereafter referred to as the ''August 25th COVID–19 IFC'') (that is scheduled to appear in the September 2, 2020 **Federal Register**). Pursuant to the August 25th COVID–19 IFC, no claims data or chart-abstracted data reflecting services provided January 1, 2020–June 30, 2020 will be used in calculations for the Hospital VBP Program due to the COVID–19 PHE. Please refer to the August 25th COVID–19 IFC for more details.

b. Person and Community Engagement Domain

Since the FY 2015 program year, we have adopted a 12-month baseline period and a 12-month performance period for measures in the Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the Person and Community Engagement domain that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and subsequent years.

We did not propose any changes to these policies.

c. Clinical Outcomes Domain

For the FY 2020 and FY 2021 program years, we adopted a 36-month baseline period and a 36-month performance period for measures in the Clinical Outcomes domain (previously referred to as the Clinical Care domain) (79 FR 50073; 80 FR 49563 through 49564). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also adopted a 22-month performance period and a 36-month baseline period specifically for the MORT–30–PN (updated cohort) measure for the FY 2021 program year.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we adopted a 36-month performance period and a 36-month baseline period for the FY 2022 program year for each of the previously finalized measures in the Clinical Outcomes domain—that is, the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, COMP–HIP–KNEE, and MORT–30–CABG measures. In the same final rule (81 FR 57001), we adopted a 34-month performance period and a 36-month baseline period for the MORT–30–PN (updated cohort) measure for the FY 2022 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38259), we adopted a 36-month performance period and a 36-month baseline period for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort), and COMP–HIP–KNEE measures for the FY 2023 program year and subsequent years. Specifically, for the mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, and MORT–30–PN (updated cohort)), the performance period runs for 36 months from July 1, 5 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year, and the baseline period runs for 36 months from July 1, 10 years prior to the applicable fiscal program year, to June 30, 7 years prior to the applicable fiscal program year. For the COMP–HIP–KNEE measure, the performance period runs for 36 months from April 1, 5 years prior to the applicable fiscal program year, to March 31, 2 years prior to the applicable fiscal program year, and the baseline period runs for 36 months from April 1, 10 years prior to the applicable fiscal program year, to March 31, 7 years prior to the applicable fiscal program year.

We did not propose any changes to the length of these performance or baseline periods.

d. Safety Domain

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure—that runs on the calendar year 2 years prior to the applicable program year and a baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent program years.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38258), for the FY 2023 program year, we adopted a 21-month baseline period (October 1, 2015 to June 30, 2017) and a 24-month performance period (July 1, 2019 to June 30, 2021) for the CMS PSI 90 measure. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38258 through 38259), we adopted a 24-month performance period and a 24-month baseline period for the CMS PSI 90 measure for the FY 2024 program year and subsequent years. Specifically, the performance period runs from July 1, 4 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year, and the baseline period runs from July 1, 8 years prior to the applicable fiscal program year, to June 30, 6 years prior to the applicable fiscal program year.

We did not propose any changes to these policies.

e. Efficiency and Cost Reduction Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and a 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the MSPB measure that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent years.

We did not propose any changes to these policies.

f. Summary of Previously Adopted Baseline and Performance Periods for the FY 2023 Through FY 2026 Program Years

These tables summarize the baseline and performance periods that we have previously adopted.

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[436] Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19. Available at: *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

Baseline and Performance Periods for the FY 2023 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement • HCAHPS	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) • COMP-HIP-KNEE	• July 1, 2013 – June 30, 2016 • April 1, 2013 – March 31, 2016	• July 1, 2018 – June 30, 2021* • April 1, 2018 – March 31, 2021*
Safety • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) • CMS PSI 90	• January 1, 2019 – December 31, 2019 • October 1, 2015 – June 30, 2017	• January 1, 2021 – December 31, 2021 • July 1, 2019 – June 30, 2021*
Efficiency and Cost Reduction • MSPB	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021

* These performance periods are impacted by the ECE granted by CMS on March 22, 2020, further specified by CMS on March 27, 2020 and amended in the August 25th COVID-19 IFC . For more detailed information, see section IV.L.3.a. of the preamble of this final rule.

Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement • HCAHPS	• January 1, 2020 – December 31, 2020*	• January 1, 2022 – December 31, 2022
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) • COMP-HIP-KNEE	• July 1, 2014 – June 30, 2017 • April 1, 2014 – March 31, 2017	• July 1, 2019 – June 30, 2022* • April 1, 2019 – March 31, 2022*

Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Safety • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) • CMS PSI 90	• January 1, 2020 – December 31, 2020* • July 1, 2016 – June 30, 2018	• January 1, 2022 – December 31, 2022 • July 1, 2020 – June 30, 2022
Efficiency and Cost Reduction • MSPB	• January 1, 2020 – December 31, 2020*	• January 1, 2022 – December 31, 2022

* These performance periods are impacted by the ECE granted by CMS on March 22, 2020, further specified by CMS on March 27, 2020, and amended in the August 25th COVID-19 IFC. For more detailed information, see section IV.L.3.a. of the preamble of this final rule.

Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement • HCAHPS	• January 1, 2021 – December 31, 2021	• January 1, 2023 – December 31, 2023
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) • COMP-HIP-KNEE	• July 1, 2015 – June 30, 2018 • April 1, 2015 – March 31, 2018	• July 1, 2020 – June 30, 2023 • April 1, 2020 – March 31, 2023*
Safety • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) • CMS PSI 90	• January 1, 2021 – December 31, 2021 • July 1, 2017 – June 30, 2019	• January 1, 2023 – December 31, 2023 • July 1, 2021 – June 30, 2023
Efficiency and Cost Reduction • MSPB	• January 1, 2021 – December 31, 2021	• January 1, 2023 – December 31, 2023

Baseline and Performance Periods for the FY 2026 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2016 – June 30, 2019 ● April 1, 2016 – March 31, 2019	● July 1, 2021 – June 30, 2024 ● April 1, 2021 – March 31, 2024
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2022 – December 31, 2022 ● July 1, 2018 – June 30, 2020*	● January 1, 2024 – December 31, 2024 ● July 1, 2022 – June 30, 2024
Efficiency and Cost Reduction ● MSPB	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024

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4. Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures involved, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42396) for previously established performance standards for the FY 2022 program year.

We note that the performance standards for all of the following measures are calculated with lower values representing better performance:

- CDC NHSN HAI measures (CLABSI, CAUTI, CDI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI).
- CMS PSI 90 measure.
- COMP–HIP–KNEE measure.
- MSPB measure.

This distinction is made in contrast to other measures—HCAHPS and the mortality measures, which use survival rates rather than mortality rates—for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we first award achievement and improvement points to each stratum separately, and then compute a weighted average of the points awarded to each stratum by predicted infections.

b. Previously Established and Estimated Performance Standards for the FY 2023 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38264 through 38265), we established performance standards for the FY 2023 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41471 through 41472), we established, for the FY 2023 program year, the performance standards for the Safety domain measure, CMS PSI 90. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32775 through 32777), in accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we estimated additional performance standards for the FY 2023 program year. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32775), we noted that the numerical values for the performance standards for the Safety and Person and Community Engagement domains for the FY 2023 program year were estimates based on the most recently available data, and that we intended to update the numerical values in the FY 2021 IPPS/LTCH PPS final rule.

The previously established and newly established performance standards for the measures in the FY 2023 program year are set out in these tables.

Previously Established and Newly Established Performance Standards for the FY 2023 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
CMS PSI 90*#	0.972658	0.760882
CAUTI*♦	0.676	0
CLABSI*♦	0.596	0
CDI*♦	0.544	0.01
MRSA Bacteremia*♦	0.727	0
Colon and Abdominal Hysterectomy SSI*♦	0.734 0.732	0 0
Clinical Outcomes Domain		
MORT-30-AMI#	0.866548	0.885499
MORT-30-HF#	0.881939	0.906798
MORT-30-PN (updated cohort)#	0.840138	0.871741
MORT-30-COPD#	0.919769	0.936349
MORT-30-CABG#	0.968747	0.979620
COMP-HIP-KNEE*#	0.027428	0.019779
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

Previously established performance standards.

♦ The newly established performance standards displayed in this table for the CDC NHSN measures (CAUTI, CLABSI, CDI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) were calculated using four quarters of CY 2019 data.

The eight dimensions of the HCAHPS measure are calculated to generate the HCAHPS Base Score. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points.

Newly Established Performance Standards for the FY 2023 Program Year: Person and Community Engagement Domain±			
HCAHPS Survey Dimension	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	53.50	79.42	87.71
Communication with Doctors	62.41	79.83	87.97
Responsiveness of Hospital Staff	40.40	65.52	81.22
Communication about Medicines	39.82	63.11	74.05
Hospital Cleanliness & Quietness	45.94	65.63	79.64
Discharge Information	66.92	87.23	92.21
Care Transition	25.64	51.84	63.57
Overall Rating of Hospital	36.31	71.66	85.39

± The newly established performance standards displayed in this table were calculated using four quarters of CY 2019 data.

c. Previously Established Performance Standards for Certain Measures for the FY 2024 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472), we established performance standards for the FY 2024 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42395 through 42398), we established, for the FY 2024 program year, the performance standards for the Safety domain measure, CMS PSI 90. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in this table.

Previously Established Performance Standards for the FY 2024 Program Year		
Measure Short Name	Achievement Threshold	Benchmark
Safety Domain		
CMS PSI 90*	0.968841	0.754176
Clinical Outcomes Domain		
MORT-30-AMI	0.869247	0.887868
MORT-30-HF	0.882308	0.907733
MORT-30-PN (updated cohort)	0.840281	0.872976
MORT-30-COPD	0.916491	0.934002
MORT-30-CABG	0.969499	0.980319
COMP-HIP-KNEE*	0.025396	0.018159
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

d. Previously Established and Newly Established Performance Standards for Certain Measures for the FY 2025 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2025 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance

period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are establishing performance standards for the CMS PSI 90 measure for the FY 2025 program year. The previously established and newly established performance standards for these measures are set out in this table.

Previously Established and Newly Established Performance Standards for the FY 2025 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
CMS PSI 90*	0.964854	0.753807
Clinical Outcomes Domain		
MORT-30-AMI#	0.872624	0.889994
MORT-30-HF#	0.883990	0.910344
MORT-30-PN (updated cohort) #	0.841475	0.874425
MORT-30-COPD#	0.915127	0.932236
MORT-30-CABG#	0.970100	0.979775
COMP-HIP-KNEE*#	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

Previously established performance standards.

e. Newly Established Performance Standards for Certain Measures for the FY 2026 Program Year

As previously discussed, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), and our performance standards definitions codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2026 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in this table.

Newly Established Performance Standards for the FY 2026 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Clinical Outcomes Domain		
MORT-30-AMI	0.874426	0.890687
MORT-30-HF	0.885949	0.912874
MORT-30-PN (updated cohort)	0.843369	0.877097
MORT-30-COPD	0.914691	0.932157
MORT-30-CABG	0.970568	0.980473
COMP-HIP-KNEE*	0.024019	0.016873
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

We received several public comments on our newly established performance periods for FY 2024 through FY 2026.

Comment: A few commenters expressed their support for the newly established performance standards for certain measures for the FY 2023 through FY 2026 program years.

Response: We thank commenters for their support.

After consideration of the public comments that we received, we are establishing the performance standards for the FY 2023 through FY 2026 program years as previously discussed.

5. Scoring Methodology and Data Requirements

a. Domain Weighting for the FY 2022 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we adopted a policy to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. We did not propose any changes to these domain weights.

b. Domain Weighting for the FY 2022 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), for the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted. We did not propose any changes to these domain weights.

c. Minimum Numbers of Measures for Hospital VBP Program Domains

Based on our previously finalized policies (82 FR 38266), for a hospital to receive domain scores:

- A hospital must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Person and Community Engagement domain score.
- A hospital must receive a minimum of two measure scores within the Clinical Outcomes domain to receive a Clinical Outcomes domain score.
- A hospital must receive a minimum of two measure scores within the Safety domain to receive a Safety domain score.
- A hospital must receive a minimum of one measure score within the Efficiency and Cost Reduction domain to receive an Efficiency and Cost Reduction domain score.

We did not propose any changes to these policies.

d. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41465 through 41466); and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42399 through 42400). We did not propose any changes to these policies.

(2) Summary of Previously Adopted Minimum Numbers of Cases

The previously adopted minimum numbers of cases for these measures are set forth in this table.

Previously Adopted Minimum Case Number Requirements for the FY 2023 Program Year and Subsequent Years	
Measure Short Name	**Minimum Number of Cases**
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CMS PSI 90	Hospitals must report a minimum of three eligible cases on any one underlying indicator.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

e. Summary of Previously Adopted Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42400 through 42402), we finalized our proposal for the Hospital VBP Program to use the same data to calculate the CDC NHSN HAI measures that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020[437] for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402), we also finalized our proposal for the Hospital VBP Program to use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and to rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We did not propose any changes to these policies in the proposed rule.

We refer readers to section IV.M. of the preamble of this final rule for additional information about HAC Reduction Program refinements to validation policies for the CDC NHSN HAI measures.

6. Overall Hospital Quality Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), we proposed a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). The Overall Star Rating would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital VBP Program. We refer readers to section XVI of the CY 2021 OPPS/ASC proposed rule for details.

M. Hospital-Acquired Conditions (HAC) Reduction Program: Updates and Changes (§ 412.170)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104).
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026).
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492).
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411).

These rules describe the general framework for the HAC Reduction Program's implementation, including: (1) The relevant definitions applicable to the program; (2) the payment adjustment under the program; (3) the measure selection process and conditions for the program, including a risk adjustment and scoring methodology; (4) performance scoring; (5) data collection; (6) validation; (7) measure removal factors policy; (8) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; (9) the extraordinary circumstances exception policy; and (10) limitation of administrative and judicial review. We remind readers that data collection and validation policies (items (5) and (6)) were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492) and further clarified in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

1. Summary of Policies for the HAC Reduction Program

In section IV.M.4. of the preamble of this final rule, we discuss the automatic adoption of applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary. In section IV.M.6. of the preamble of this final rule, we discuss

[437] Pursuant to the August 25th COVID–19 IFC, no claims data or chart-abstracted data reflecting services provided January 1, 2020–June 30, 2020 will be used in calculations for the Hospital Value-Based Purchasing Program among other Medicare quality reporting and value-based purchasing programs due to the COVID–19 Public Health Emergency. Please refer to the August 25th COVID–19 IFC for more details.

our refinements to the HAC Reduction Program validation procedures. Finally, in section IV.M.7. of the preamble of this final rule, we discuss our update to the definition of *applicable period* at 42 CFR 412.170 to align with our finalized changes. We note that we received public comments related to the structure of the program, its measures, and the overall Medicare quality evaluation strategy for the HAC Reduction Program in response to the FY 2021 IPPS/LTCH PPS proposed rule. While we appreciate the commenters' feedback, because we did not include any proposals related to these topics in the proposed rule, we consider the public comments to be out of the scope of the proposed rule. However, all topics that we consider to be out of scope of the proposed rule will be taken into consideration when developing policies and program requirements for future years.

2. Measures for FY 2021 and Subsequent Years

a. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we also finalized the use of the CMS PSI 90 measure. These previously finalized measures, with their full measure names, are shown in this table.

HAC Reduction Program Measures for FY 2021 and Subsequent Years

Short Name	Measure Name	NQF #
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at: *https://www.qualitynet.org/inpatient/measures/psi/resources*. Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In this final rule, we note that we did not propose to adopt or remove any measures.

b. Measure Removal Factors Policy

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Initiative. We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. In this final rule, we note that we did not propose any measure removal and retention factor policy changes.

4. Applicable Period for the HAC Reduction FY 2023 Program Year and Subsequent Years

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we believe that using 24-month data collection periods for the CMS PSI 90 and CDC NHSN HAI measures for the HAC Reduction Program provides hospitals and the general public the most current data available. The 24-month data period also allows time to complete the complex calculation process for these measures, to perform comprehensive quality assurance to enhance the accuracy of measure results, and to disseminate confidential reports on hospital-level results to individual hospitals. Though we had truncated the applicable period to shorter than a 24-month data collection period for the CMS PSI 90 to accommodate the transition to the ICD–10 classification system for FY 2018 and 2019, we returned to using the full 24-month data collection period as soon as the ICD–10 transition was complete. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38271), for FY 2020, we finalized the applicable period for the CMS PSI 90 as the 24-month period from July 1, 2016 through June 30, 2018. Additionally, we finalized the applicable period for the CDC NHSN HAI measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), as the 24-month period from January 1, 2017 through December 31, 2018. We have finalized the 24-month applicable

periods for FYs 2021 and 2022 [438] consistent with these applicable periods and with the definition specified at 42 CFR 412.170.

In order to provide greater certainty around future applicable periods for the HAC Reduction Program, we proposed the automatic adoption of applicable periods for the FY 2023 program year and all subsequent program years for the HAC Reduction Program. Beginning in FY 2023, the applicable period for both the CMS PSI 90 and CDC NHSN HAI measures will be the 24-month period beginning 1 year advanced from the previous program year's start of the applicable period. That is, for FY 2023, the applicable period for the CMS PSI 90 would be the 24-month period from July 1, 2019 through June 30, 2021, and the applicable period for CDC NHSN HAI measures would be the 24-month period from January 1, 2020 through December 31, 2021, which is advanced 1 year from the applicable period for the FY 2022 HAC Reduction Program.[439] All subsequent years would advance this 24-month period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. We believe that the automatic adoption of the applicable period each year would streamline the process and provide additional clarity and consistency to the Program.

We invited public comment on our proposal to automatically adopt applicable periods for the Program beginning with the FY 2023 program year. We received several public comments on our proposal for the automatic adoption of applicable periods for the HAC Reduction Program.

Comment: Several commenters expressed support for the automatic adoption of applicable periods. Some of these commenters viewed this proposal as a minimal change and noted that this proposal would provide continuity and consistency for future program years.

Response: We thank the commenters for their support.

Comment: One commenter noted that in the proposed rule we stated that the 24-month period for CDC NHSN HAI measures in the FY 2023 program year would be January 1, 2020 through December 31, 2022. They noted that the timeframe we provided was 3 years and questioned if we meant to say January 1, 2020 through December 31, 2021.

Response: We thank the commenter for their correction and agree that the applicable period for the CDC NHSN HAI measures for the FY 2023 program year should be January 1, 2020 through December 31, 2021. That updated period is reflected in the previous text.

After consideration of the public comments that we received, we are finalizing our proposal to automatically adopt applicable periods for the HAC Reduction Program beginning with the FY 2023 program year.

5. HAC Reduction Program Scoring Methodology and Scoring Review and Correction Period

In FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we adopted the Equal Measure Weights approach to scoring and clarified the ''Scoring Calculations Review and Correction Period'' (83 FR 41484). Hospitals must register for a QualityNet Secure Portal account in order to access their annual hospital-specific reports. We will continue using this scoring methodology and the ''Scoring Calculations Review and Correction Period'' process in FY 2021 and for subsequent years. In this final rule, we note that we did not propose any changes to the HAC Reduction Program scoring methodology or Scoring Calculations Review and Correction Period.

6. Validation of HAC Reduction Program Data

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program, because the Hospital IQR Program finalized its proposals to remove the CDC NHSN HAI measures from its program. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), we provided additional clarification to the validation selection and scoring methodology. We also refer readers to the *QualityNet* website for more information regarding chart-abstracted data validation of measures.

In the FY 2019 IPPS/LTCH PPS final rule, we finalized our policy that the FY 2023 HAC Reduction Program will begin validation with Q3 2020 discharges, which must be reported by February 2021 using the following validation schedule.

[438] FY 2019 IPPS/LTCH PPS final rule (83 FR 41489); FY 2020 IPPS/LTCH PPS final rule (84 FR 42410).

[439] Pursuant to [August 25th COVID IFC, no claims and chart-abstracted data reflecting services provided January 1, 2020–June 30, 2020 will be used in calculations for the HAC Reduction Program and other value-based purchasing and quality reporting programs, and some data has been made optional because of the COVID 19 PHE. For more details on the impact to scoring, please refer to the CMS–3401–IFC: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency.

Finalized Validation Period for the HAC Reduction Program in FY 2023 [*Dates are subject to change]					
Discharge Quarters by Fiscal Year (FY)	**Current CDC NHSN HAI Submission Deadline***	**Current CDC NHSN HAI Validation Templates***	**Estimated CDAC[440] Record Request**	**Estimated Date Records Due to CDAC**	**Estimated Validation Completion**
Q1 2020	08/15/2020				
Q2 2020	11/15/2020				
Q3 2020^	**02/15/2021**	**02/01/2021**	**02/28/2021**	**03/30/2021**	**06/15/2021**
Q4 2020^	**05/15/2021**	**05/01/2021**	**05/30/2021**	**06/29/2021**	**09/15/2021**
Q1 2021^	**08/15/2021**	**08/01/2021**	**08/30/2021**	**09/29/2021**	**12/15/2021**
Q2 2021^	**11/15/2021**	**11/01/2021**	**11/29/2021**	**12/29/2021**	**03/15/2022**

Bolded rows with dates in each column, denoted with the ^ symbol next to the date in the Discharge Quarter by Fiscal Year (FY) column, indicate the HAC Reduction Program validation cycle for the FY 2023 program.

We also adopted a policy that any nonsubstantive updates to the procedures for measure validation of chart-abstracted measures will be provided on the *QualityNet* website.

We proposed several changes to the process for validation of HAC Reduction Program measure data to align this program with the proposed changes to the Hospital IQR Program measure validation process. Specifically, we will align the hospital selection and submission quarters beginning with FY 2024 Hospital IQR and HAC Reduction Programs' validation so that we only require one pool of hospitals to submit data for validation. We believe that this would reduce burden and streamline processes. Our specific proposals to update the HAC Reduction Program validation process are described later in this section. For more information on the finalized updates to the Hospital IQR Program measure validation process, see section VIII.A. of the preamble of this final rule.

b. Updates to Processes for Validation of HAC Reduction Program Measure Data

(1) Aligning Submission Quarters to Hospital IQR Submissions

To support the transition to an aligned validation process for the HAC Reduction Program and the Hospital IQR Program, we proposed to change the quarters of data used for HAC Reduction Program measure validation. Under the existing validation structure, hospitals selected for validation for the FY 2023 program year would be required to submit HAC Reduction Program measure data from the third and fourth quarters of 2020 and the first and second quarters of 2021 (as depicted in the table in section IV.M.6.a. of the preamble of this final rule).

In order to align the quarters used for HAC Reduction Program and Hospital IQR validation, we proposed to only use measure data from the third and fourth quarters of 2020 for the FY 2023 program year (illustrated in this table). We will use measure data from only these quarters for both the random and targeted validation pools.

Aligned Quarters Used for Validation for FY 2023	
Fiscal Year 2023	**Quarter**
HAC Reduction Program Data	3Q 2020
	4Q 2020

For the FY 2024 program year and subsequent years, we proposed to use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program. Under this approach, the data submission deadlines for chart-abstracted measures will be in the middle of the month, the fifth month following the end of the reporting quarter.

Aligned Quarters Used for Validation for FY 2024 and Subsequent Years	
Fiscal Year 2024	**Quarter**
HAC Reduction Program Data	1Q 2021
	2Q 2021
	3Q 2021
	4Q 2021

[440] The CMS Clinical Data Abstraction Center (CDAC) performs the validation.

We invited public comment on our proposed revision to the validation period for the FY 2023 program year and alignment of the quarters of data used for validation with the Hospital IQR Program beginning with validation for the FY 2024 program year. We received several public comments on the proposals to align the quarters of validation for the HAC Reduction Program and Hospital IQR Program.

Comment: Several commenters supported the proposal to align the quarters of validation for the HAC Reduction Program and Hospital IQR Program.

Response: We thank the commenters for their support of the proposal to revise the validation period for the FY 2023 program year and alignment the quarters used for validation beginning with validation for the FY 2024 program year.

Comment: One commenter recommended limiting the chart-abstracted validation to one calendar quarter and reducing the number of hospitals selected during the validation process in order to reduce provider burden.

Response: While we agree with this commenter that restricting data validation to fewer calendar quarters may lead to some reduction to provider burden, we do not believe that such a restriction would be consistent with our approach which has been designed to increase opportunities to detect poor reporting (77 FR 53540). Additionally, requiring fewer quarters of data for validation, by reducing sample size, would impede the calculation of statistically sound validation scores needed to make payment determinations.

After consideration of the public comments we received, we are finalizing our proposals to revise the validation period for the FY 2023 HAC Reduction Program to Q3 2020 and Q4 2020, and to align the quarters used for validation with the Hospital IQR Program beginning with validation of data from the first quarter of 2021 for the FY 2024 program year.

(2) Aligning Hospital Selection

Currently, a total of up to 600 hospitals may be selected for validation under the HAC Reduction Program. This is achieved by the HAC Reduction Program taking an annual sample of up to 400 randomly selected hospitals and selecting up to 200 hospitals using targeting criteria. We did not propose any changes to the hospital selection for validation for the FY 2023 program year. However, we proposed to update the policies to reduce the total validation pool from up to 600 hospitals to up to 400 hospitals, effective beginning with validation for the FY 2024 program year. This would align with proposed changes for by the Hospital IQR Program as described in section VIII.A. of the preamble of this final rule. To achieve this reduction, we proposed reducing the randomly selected hospital pool from up to 400 hospitals to up to 200 hospitals for validation for the FY 2024 program year and subsequent years. We note that these will be the same hospitals as those selected for validation under the Hospital IQR Program to the extent that the Hospital IQR Program has measures for those hospitals; therefore, we will be selecting a total of up to 400 hospitals across both the HAC Reduction Program and the Hospital IQR Program. This would reduce the total number of hospitals selected for validation across both programs by approximately one third each year. We believe reducing the total number of hospitals randomly selected for chart-abstracted measure validation to up to 200 will maintain a sufficient sample size for a statistically meaningful estimate of hospitals' reporting accuracy and help streamline the process for both programs.

We invited public comment on our proposed revision to align hospital selection for validation with the Hospital IQR Program beginning with validation for the FY 2024 program year. We received several public comments on reducing the number of hospitals selected for chart-abstracted validation under the HAC Reduction and Hospital IQR Programs from up to 600 to up to 400.

Comment: Several commenters supported the proposal to reduce the number of hospitals selected for chart-abstracted validation under the HAC Reduction and Hospital IQR Programs from up to 600 to up to 400.

Response: We thank the commenters for their support of the proposal to reduce the number of hospitals selected for validation from up to 600 to up to 400.

Comment: We received one comment requesting that the number of hospitals selected for validation be further limited from up to 400 to up to 200. The commenter requested that CMS take as many steps as possible to minimize provider reporting burden as providers continue to face disruption to care delivery during the COVID–19 public health emergency.

Response: Because the minimum sample size required to assess the percentage of hospitals in the HAC Reduction Program depends on the expected percentage of hospitals that fail validation, we do not believe that we can reduce the number of selected hospitals in this section of this rule to up to 200 at this time. We will continue to evaluate the number of hospitals required to be confident that hospitals in the HAC Reduction Program population are achieving the requisite reliability score.

After consideration of the public comments we received, we are finalizing our proposal to reduce the total number of hospitals selected for validation under the HAC Reduction Program from up to 600 to up to 400 beginning with the FY 2024 program year, that is, for data beginning with calendar year 2021.

(3) Requiring the Use of Digital Submissions for Medical Records Requests

We proposed to require hospitals to submit digital files when submitting medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years. Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation or they may submit patient charts for validation by securely transmitting electronic versions of medical information (83 FR 41478 through 41484). Currently, submission via secure transmission can either entail downloading or copying the digital image of the patient chart onto CD, DVD, or flash drive, or submission of PDFs using a CMS-approved secured file transfer system.

In the FY 2021 IPPS/LTCH PPS proposed rule, in alignment with proposals made for the Hospital IQR Program in the same proposed rule, we proposed to discontinue the option of sending CD, DVD, or flash drives containing digital images of patient charts, beginning with Q1 2021 for FY 2024 program year validation. Under this approach, hospitals would be required to submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process. We would continue to reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

We discussed in the proposed rule that we strive to provide the public with accurate quality data while maintaining alignment with hospital recordkeeping practices. We appreciate that hospitals have rapidly adopted EHR systems as their primary source of information about patient care, which can facilitate the process of producing electronic copies of medical records (78 FR 50834).

Additionally, we monitor the medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor, and have found almost two-thirds of providers use the option to submit PDF copies of medical records as electronic files. We noted that paper submissions can be reimbursed at a higher rate than for electronic submissions, especially for longer records because paper submissions are reimbursed on a per page basis, while electronic submissions are reimbursed using a flat rate for each submission. In our assessment based on the monitoring, we believe the electronic submissions can be a more effective and efficient process for the hospitals selected for validation. Requiring electronic file submissions reduces the burden of not only coordinating numerous paper-based pages of medical records and making photocopies, but also shipping it to the CDAC. Therefore, we stated we believe it is appropriate to require that hospitals use electronic submissions via a CMS-approved secure file transmission process.

We invited public comment on this proposed requirement to electronically submit medical records for validation. We received several public comments related to the requirement of electronic submissions of medical records for validation beginning with data submissions of Q1 2021 discharges for FY 2024 program year validation.

Comment: Several commenters supported the requirement of electronic submissions of medical records for validation beginning with data submissions of Q1 2021 discharges for FY 2024 program year validation.

Response: We thank the commenters for their support of the transition to electronic submission of medical records.

Comment: Several commenters supported the requirement of electronic submissions of medical records for validation, but requested that the implementation be delayed a year as providers address the ongoing disruption in care delivery due to the COVID–19 public health emergency.

Response: We appreciate the commenters support for the proposal but disagree that requiring electronic file submission will be burdensome. Based on our monitoring of medical record submissions to the CDAC, we believe requiring electronic file submissions is a more effective and efficient process and will reduce burden for hospitals selected for validation, which we believe to be especially critical during the COVID–19 PHE. Medical records for Q1 2021 would be anticipated to be due around August 2021.

Comment: A commenter requested that we provide additional clarity on the processes for electronic submissions. Specifically, the commenter questioned if the format for the validation record requests to hospitals would be modified and if CMS would require all communication for the validation process to be electronic.

Response: At this time, the medical records request packets sent to the selected hospitals by the CDAC will continue to be distributed in a physical FedEx-mailed format, complemented with an electronic Case Selection Report, or the like, similar to the current process. The physical medical record request packet ensures that CMS receives a signed delivery receipt at the official physical location of the hospital.

After consideration of the public comments we received, we are finalizing our proposal to require the electronic submission of PDF copies of medical records to the CDAC for validation purposes for the HAC Reduction Program beginning with Q1 2021 discharge data for the FY 2024 program year.

7. Regulatory Updates (42 CFR 412.170)

We proposed to amend the definition of *applicable period* at 42 CFR 412.170 to align with our finalized automatic adoption of applicable periods in future program years. Section 42 CFR 412.170 currently defines *applicable period* as the 2-year period specified by the Secretary from which data are collected in order to calculate the total hospital-acquired condition score under the HAC Reduction Program. The proposed amendment to the definition will add language to specify: (1) The applicable period of the CMS PSI 90 and CDC NHSN HAI measures for the FY 2023 HAC Reduction Program; and (2) beginning with the FY 2023 program year, the applicable period will be advanced by 1 year from the prior from the prior fiscal year's applicable period. This addition to the definition at 42 CFR 412.170 makes it so applicable periods for future program years do not need to be defined during rulemaking.

We invited public comment on our proposal to amend the definition of *applicable period* at 42 CFR 412.170 to align with finalized automatic adoption of applicable periods in future program years.

We did not receive any public comments on the update to the definition of *applicable period* and are finalizing our proposed updates to the regulatory text at 42 CFR 412.170.

8. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772through 49082), we proposed a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the HAC Reduction Program. We refer readers to section XVI of the CY 2021 OPPS/ASC proposed rule for details.

N. Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Overview of Medicare Direct GME and IME

The Medicare program makes payments to teaching hospitals to account for two types of costs, the direct costs (direct GME) and the indirect costs (IME) of a hospital's graduate medical education program. Direct GME payments represent the direct costs of training residents (for example, resident salaries, fringe benefits, and teaching physician costs associated with an approved GME program) and generally are calculated by determining the product of the Medicare patient load (that is, the percentage of the hospital's Medicare inpatient days), the hospital's per resident payment amount, and the weighted number of FTE residents training at the hospital during the cost reporting period.

The IME adjustment is made to teaching hospitals for the additional indirect patient care costs attributable to teaching activities. For example, teaching hospitals typically offer more technologically advanced treatments to their patients, and therefore, patients who are sicker and need more sophisticated treatment are more likely to go to teaching hospitals. Furthermore, there are additional costs related to the presence of inefficiencies associated with teaching residents resulting from the additional tests or procedures ordered by residents and the demands put on physicians who supervise, and staff who support, the residents. IME payments are made for each inpatient discharge as a percentage add-on adjustment to the Hospital Inpatient Prospective Payment System (IPPS) payment, and are calculated based on the hospital's ratio of FTE residents to available beds as defined at § 412.105(b). The statutory formula for calculating the IME adjustment is: $c \times [(1 + r)^{.405} - 1]$, where ''r'' represents the hospital's ratio of FTE residents to beds, and ''c'' represents an IME multiplier, which is set by the Congress.

The amount of IME payment a hospital receives for a particular discharge is dependent upon the number of FTE residents the hospital trains, the hospital's number of available beds, the current level of the statutory IME multiplier, and the per discharge IPPS payment. Sections 1886(d)(5)(B)(v) and 1886(h)(4)(F) of the Act established hospital-specific limits (that is, caps) for purposes of calculating indirect and direct GME payments, respectively with regard to the number of allopathic and osteopathic FTE residents that hospitals may count.

2. Existing Regulations Related to Residency Program or Teaching Hospital Closure

The regulations at 42 CFR 413.79(h) for direct GME, and 42 CFR 412.105(f)(1)(ix) for IME, provide for a hospital that is closing or closing its residency program(s) to volunteer to temporarily transfer a portion of its hospital-specific direct GME and IME FTE resident caps to other hospitals that are willing to accept and train the displaced resident(s) for the duration of the resident's training program. CMS first implemented regulations regarding residents displaced by teaching hospital closure in the July 30, 1999 IPPS final rule (64 FR 41522). We made the change to allow a receiving hospital to receive temporary IME and direct GME cap adjustments in limited circumstances for assuming the training of displaced residents due to hospital closure, because of a reluctance on the part of receiving hospitals to assume such displaced residents without receiving increases to their IME and direct GME FTE resident caps to ensure receipt of Medicare funding. We define ''closure of a hospital'' at 42 CFR 413.79(h)(1)(i) as a situation in which the hospital terminates its Medicare agreement under the provisions of § 489.52 of this chapter. At 42 CFR 413.79(h)(2), our regulations state that a hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following conditions: The hospital is training additional residents from a hospital that closed on or after July 1, 1996, and no later than 60 days after the hospital begins to train the residents, the hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.

Subsequently, in the August 1, 2001 IPPS final rule (66 FR 39899), we further added to the regulations at 42 CFR 413.79(h) to also allow a receiving hospital to receive temporary IME and direct GME cap adjustments due to closure of a residency program (although the hospital itself would remain open) for assuming the training of displaced residents, due to similar reluctance on the part of receiving hospitals to accept these displaced residents without obtaining increases to their IME and direct GME FTE resident caps to ensure receipt of Medicare funding. We define ''closure of a hospital residency training program'' at 42 CFR 413.79(h)(1)(ii) to mean the hospital ceases to offer training for residents in a particular approved medical residency training program. However, because the hospital with the closing program itself remains open in the case of program closure, it retains its full IME and direct GME FTE resident caps. In order to prevent the situation of double payment for the same FTE resident cap slots, where the originating hospital closes a program and fills its vacated slots with residents from a different specialty, while the receiving hospital also receives payment for training the displaced resident, we stated in regulation that a receiving hospital could only receive the temporary FTE resident cap adjustment if the originating hospital with the closed program voluntarily agreed to temporarily reduce its FTE resident caps for the duration of the displaced residents' training at the receiving hospital (see 66 FR 39900 August 1, 2001). We revised the regulations at 42 CFR 413.79(h)(3) to specify the responsibilities of the closing hospital or program and the receiving hospital.

3. Policy Change Related to Medical Residents Affected by Residency Program or Teaching Hospital Closure

When teaching hospitals have closed, we receive many inquiries from concerned stakeholders about whether Medicare IME and direct GME funding could be seamlessly maintained for the medical residents that would have to find alternate training hospitals to complete their training. However, although not explicitly stated in regulations text, our current policy is that the definition of a displaced resident is one that is physically present at the hospital training on the day prior to or the day of hospital or program closure. This longstanding policy derived from the fact that in both the regulations text under hospital closure and program closure, there is a requirement that the receiving hospital identifies the residents ''who have come from the closed hospital,'' or ''identifies the residents who were in training at the time of the program's closure'' (see 42 CFR 413.79(h)(2)(ii) and (h)(3)(ii)(B)). We considered the residents who were physically present at the hospital to be those residents who were ''training at the time of the program or hospital closure,'' thereby granting them the status of ''displaced residents.'' However, stakeholders have voiced their concern that by limiting the ''displaced residents'' to only those physically present at the time of closure, it becomes much more administratively challenging for the following groups of residents at closing hospitals/programs to have their residencies continue to be funded by Medicare: (1) Residents who leave the program after the closure is publicly announced to continue training at another hospital, but before the actual closure; (2) residents assigned to and training at planned rotations at other hospitals who will be unable to return to their rotations at the closing hospital or program; and (3) individuals (such as medical students or would-be fellows) who matched into GME programs at the closing hospital or program but have not yet started training at the closing hospital or program. Other groups of residents who, under current policy, are already considered ''displaced residents'' include— (1) residents who are physically training in the hospital on the day prior to or day of program or hospital closure; and (2) residents who would have been at the closing hospital/program on the day prior to or of closure, but for the fact that they were on approved leave at that time, and will be unable to return to their training at the closing hospital/program.

We proposed to amend the Medicare policy with regard to closing teaching hospitals and closing residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and the incentives of originating and receiving hospitals with regard to seamless Medicare IME and direct GME funding. We proposed to change two aspects of the current Medicare policy. First, rather than link the Medicare temporary funding for the affected residents to the day prior to or the day of program or hospital closure, we proposed that the key day would be the day that the closure was publicly announced (for example, via a press release or a formal notice to the Accreditation Council on Graduate Medical Education (ACGME)). This would provide greater flexibility for the residents to transfer while the hospital

operations or residency programs were winding down, rather than waiting until the last day of hospital or program operation. This would address the needs of the first group of residents as previously described: Residents who would leave the program after the closure was publicly announced to continue training at another hospital, but before the day of actual closure. Second, by removing the link between Medicare temporary funding for the residents, and the day prior to or the day of program or hospital closure, we proposed to also allow funding to be transferred temporarily for the second and third group of residents who are not physically at the closing hospital/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) the closing hospital/closing program.

Thus, we proposed to revise our policy with regard to which residents can be considered ''displaced'' for Medicare temporary FTE resident cap transfer purposes in the situation where a hospital announces publicly that it is closing, and/or that it is closing a residency program(s). Specifically, we proposed to add the definition of ''displaced resident'' in new 42 CFR 413.79(h)(1)(iii) to read as set out in the regulatory text of this document.

Current IME regulations at 42 CFR 412.105(f)(1)(ix) link to the direct GME regulations at 42 CFR 413.79(h), so this regulation change would apply to the IME FTE cap transfers for displaced residents as well. In order to fully coordinate these IME regulations with the new definition of ''displaced resident,'' we proposed to slightly modify the regulations at 42 CFR 412.105(f)(1)(ix) to add the word ''displaced'' to describe residents added by a receiving hospital due to a hospital or program closure. In addition, we proposed to change another detail of the policy specific to the requirements for the receiving hospital. To apply for the temporary increase in the Medicare resident cap, the receiving hospital would have to submit a letter to its Medicare Administrative Contractor within 60 days after beginning to train the displaced residents. In the July 30, 1999 IPPS final rule (64 FR 41523), we stated that this letter must include the names and social security numbers of the displaced residents, the hospital and programs in which the residents were training previously, and the amount of the cap increase needed for each resident (based on how much the receiving hospital is in excess of its caps and the length of time for which the adjustments are needed (42 CFR 413.79(h)(2)(ii)). To reduce the amount of personally identifiable information (PII) included in these agreements, we proposed to no longer require the full social security number for each resident. However, in order to still provide enough information for the hospitals and MACs to be able to differentiate among many residents, some which may have similar names, we proposed to require the receiving hospital to include the names and the last four digits of each displaced resident's social security number.

We also noted that as under current policy, the maximum number of FTE resident cap slots that could be transferred to all receiving hospitals is the number of IME and direct GME FTE resident cap slots belonging to the hospital that has the closed program, or that is closing. Therefore, if the originating hospital is training residents in excess of its caps, then being a displaced resident does not guarantee that a cap slot will be transferred along with that resident. A closure situation does not grant the Medicare program the authority to fund additional residency slots in excess of the cap amounts at the originating hospital. If there are more displaced residents than available cap slots, the slots may be apportioned, according to the closing hospital's discretion. The decision to transfer a cap slot if one is available is voluntary and made at the sole discretion of the originating hospital (42 CFR 413.79(h)(3)(ii)). However, if the originating hospital decides to do so, then it is the originating hospital's and/or sponsor's responsibility to determine how much of an available cap slot goes with a particular resident (if any). (Also note that only to the extent a receiving hospital would exceed its FTE cap by training displaced residents would it be eligible for the temporary adjustment (66 FR 39899, § 413.79(h)(3)(i)(B)). A receiving hospital is paid for the displaced resident using its own direct GME and IME factors, that is, the same rates as those used for residents in its own programs (see 66 FR 39901 August 1, 2001).

Comment: We received many comments in support of our proposals relating to changing the policy for what constitutes a displaced resident for Medicare DGME and IME funding purposes. Commenters believed the proposals will ensure that all displaced residents are fairly considered during a temporary transfer of DGME/IME FTE cap slots. However, two national associations believed CMS should have been more generous in its proposals, by making the new definition of ''displaced resident'' effective retroactively. One of these commenters stated that CMS should make the effective date retroactive to 2015, to send a strong message of support to residents. The other commenter stated that CMS should make the effective date retroactive to the summer of 2019 when Hahnemann University Hospital closed. This commenter argued that CMS could use authority under section 1871(e)(1)(A)(ii) of the Social Security Act (the Act), which states that a substantive change in regulations shall not be applied retroactively unless the failure to apply the change retroactively would be contrary to the public interest. This commenter believed that failure to apply this change to the regulation retroactively would be contrary to the public interest. In the case of Hahnemann University Hospital, the commenter argued that hundreds of residents were displaced and needed to quickly find alternative positions at other hospitals or risk being unable to become Board certified physicians. In addition, it would be in the public interest for these hospitals to receive DGME and IME funding for taking in these residents.

Response: We appreciate the support received for our proposals, and agree that all displaced residents will have a fair chance of receiving a temporary cap transfer when residency programs or teaching hospitals close in the future. Section 1871(e)(1)(A) of the Act permits retroactive application of a substantive change to a regulation if the Secretary determines that such retroactive application is necessary to comply with statutory requirements or that failure to apply the change retroactively would be contrary to the public interest. Here, retroactive application of the change to the definition of displaced resident is not necessary to comply with statutory requirements, nor would retroactive application at this point a year later assist those residents who, at the time of Hahnemann University Hospital's closure, according to the commenter, had ''to quickly find alternative positions at other hospitals or risk being unable to become Board certified physicians,'' since we are currently unaware of residents who did not find new training sites. Therefore, we are not accepting the commenters' request to make the effective date of these proposals retroactive.

Comment: A commenter appreciated CMS's proposal to link the Medicare temporary funding for the affected residents to the day that the closure is publicly announced (for example, via a press release or a formal notice to the Accreditation Council on Graduate Medical Education (ACGME)), but the commenter requested that CMS should

modify this proposal to include an ''outer boundary'' of 30 to 60 days *prior* to the actual program or hospital closure. The commenter believed this would prevent situations where, if the closure is announced far in advance of the actual closure, the residents may depart too early, leaving the remaining program(s) and patient care in disarray.

Response: We appreciate the challenges on multiple fronts that closing hospitals may face, particularly with regard to ensuring provision of proper patient care in a safe and efficient manner while operations wind down. While it may be possible that there could be some unforeseen consequences of our proposals relating to broadening the definition of what constitutes a ''displaced resident,'' we believe it is prudent not to further restrict this definition by instituting an ''outer boundary'' of time which would limit the timeframe that a resident may choose to depart the closing program or hospital and relocate to another teaching hospital. We believe that decisions regarding the timing of how to wind down operations and when and to where displaced residents should be relocated are best left to the hospital, program directors, and residents, and should not be mandated by federal regulation. Therefore, we are not linking Medicare temporary funding to only residents that depart a closing hospital or program within a predetermined ''outer boundary'' of time.

Comment: A few commenters requested that CMS institute a rule that when teaching hospitals close, the IME and DGME FTE resident caps would be automatically divided and assigned to each resident that is seeking an alternative hospital in which to complete his/her training. A commenter specified that keeping the authority to divide the FTE resident caps in the hands of the closing hospital only serves to increase the anxiety and uncertainty of the affected residents. The commenters believed that CMS should mitigate the anxiety and uncertainty faced by residents training in a closing hospital, by removing the authority to divide the cap from the closing hospital, and by instituting a predetermined process whereby each cap slot is equally divided among all residents seeking an alternative training home. Another option stated by one of the commenters was to require closing hospitals to formalize cap transfers ten days *after* the closure announcement.

Response: Under existing regulations, if there are more displaced residents than available cap slots, the slots may be apportioned according to the closing hospital's discretion. The decision to transfer a cap slot if one is available is voluntary and made at the sole discretion of the originating hospital (42 CFR 413.79(h)(3)(ii)). However, if the originating hospital decides to do so, then it is the originating hospital's and/or sponsor's responsibility to determine how much of an available cap slot goes with a particular resident (if any). We appreciate the commenters' desire to mitigate the uncertainty and disruption experienced by residents in the situation of a closing teaching hospital. While an automatic equal division of the IME and DGME FTE resident caps among all residents seeking alternative training sites (that is, total number of FTE residents at the closing hospital divided by the closing hospital's IME and DGME FTE Resident caps, respectively) may seem like a simple and fair approach, this could result in an advanced resident displaced in the final months of his/her training receiving the same amount of FTE resident cap as a resident displaced within his/her first year of training. In other words, a resident in his/her final months of training requires less of a share of the FTE resident cap, while a resident still at the beginning of his/her residency training requires a larger share of the FTE resident cap; therefore, assigning both the advanced resident and the new resident the same amount of FTE resident cap may, in fact, be inequitable. Therefore, we are not adopting the automatic and equal division policy offered by the commenters. With respect to the timeline for the cap transfer, CMS, through regulation, has provided hospitals with the flexibility to temporarily transfer Medicare funded FTE resident caps. We believe that the details of the transfer of FTE resident cap slots (such as when to release slots, the amount of slots to release per each resident, and so forth) be left in the hands of the closing hospital and/or the sponsor of the residency program(s) who are familiar with the dynamics of their own residency programs. Furthermore, we believe that organizations representing the interests of residents and overseeing the actual operation of residency programs are in a better position to establish rules regarding treatment of residents and their rights in the circumstance of a program or teaching hospital closure. Therefore, we are not adopting the commenters' recommendations to require automatic and equal division of the FTE resident caps upon hospital closure, nor are we requiring that FTE resident cap transfers be formalized within a certain number of days after the announcement of a hospital closure.

Comment: A commenter urged CMS to work with the Accreditation Council for Graduate Medical Education (ACGME) to establish regulations that protect residents and fellows impacted by sudden program or hospital closure. These regulations should include:

- Notice by the training hospital, intending to file for bankruptcy within 30 days, to all residents and fellows primarily associated with the training hospital, as well as those contractually matched at that training institution who may not yet have matriculated, of its intention to close, along with provision of reasonable and appropriate procedures to assist current and matched residents and fellows to find and obtain alternative training positions that minimize undue financial and professional consequences, including but not limited to maintenance of specialty choice, length of training, initial expected time of graduation, location and reallocation of funding, and coverage of tail medical malpractice insurance that would have been offered had the program or hospital not closed; and
- Protections against discrimination among displaced residents and fellows on the basis of sex, age, race, creed, national origin, gender identity, or sexual orientation.

Response: We do not believe it is CMS's role to regulate program requirements or advocate on behalf of the residents themselves. As previously stated, we believe that organizations representing the interests of residents and overseeing the actual operation of residency programs are in a better position to establish rules regarding treatment of residents and their rights in the circumstance of a program or teaching hospital closure.

Comment: Some commenters recalled the increased concern and uncertainty experienced by residents at Hahnemann University Hospital, when the hospital closure was announced and the sale of Hahnemann University Hospital's IME and DGME FTE resident cap slots to other hospitals was proffered as a possibility. These commenters requested that CMS clarify that selling of residency cap slots from one hospital to another is not permissible.

Response: CMS and closing teaching hospitals that participate in the Medicare program must abide by the Medicare statute, specifically section 1886(h)(4)(H)(vi) which provides for the redistribution of the closed teaching hospital's IME and DGME FTE resident cap slots to other eligible hospital(s) according to specific criteria. The sale or

auctioning off of Medicare funded IME and DGME FTE resident cap slots is in direct conflict with section 1886(h)(4)(H)(vi) of the Act.

Comment: A commenter requested that CMS require the MACs to formally respond to and approve requests for temporary cap adjustments made to the MACs by hospitals taking in displaced residents under 42 CFR 413.79(h). The commenter stated that such approvals would smooth future audit work, which happens several years after the actual cost report year in which the hospital took in the displaced residents, particularly in the case where the MAC may change.

Response: We appreciate the challenges that may arise for both hospitals and MACs, because as is often the nature of audits, the audits occur 2 years or more after a cost report is submitted. However, we are uncertain of the value of MAC approval of temporary cap adjustment requests shortly after the submission of those requests by hospitals taking in displaced residents. This is because the total amount of the temporary cap increase and the amount of displaced cap applicable to each displaced FTE resident training at the requesting hospital can only be verified based on review of rotation schedules documenting where and for how much time each displaced resident ultimately trained at each receiving hospital. Review of such documentation, which is detailed in nature, can only occur during a cost report audit, as it would interfere with the normal day to day reimbursement activities of the MACs. However, we will consider whether this commenter's request would be beneficial to MACs and hospitals.

Comment: A commenter noticed CMS's clarifying statement in the proposed rule that under current policy, the maximum number of FTE resident cap slots that could be transferred to all receiving hospitals is the number of IME and direct GME FTE resident cap slots belonging to the hospital that has the closed program, or that is closing (85 FR 32786). Based upon this clarifying statement of the current policy, the commenter believes that additional corresponding regulatory text may be warranted under 42 CFR 413.79(h)(2) for the closure of a hospital in order to require receiving hospitals of displaced residents to submit a copy of a signed and dated voluntary FTE transfer statement from the closing hospital. While this requirement is noted in the regulatory text under 42 CFR 413.79(h)(3) as being applicable for the closure of a hospital's residency training program, it is not noted as being applicable to a closure of a hospital situation under 42 CFR 413.79(h)(2).

Response: The commenter is pointing out a deliberate distinction between the regulations text for closing hospitals as compared to hospitals remaining open but just closing a residency program(s). In the case of a closing hospital, since there is no concern that the hospital will close a program, only to fill the vacated residency slots with residents from another program, and since the closing hospital's Medicare provider agreement along with the IME and DGME FTE resident caps will terminate, there would be no remaining resident caps to ''voluntarily'' agree to reduce. Therefore, the responsibility to notify the respective MAC lies only with the receiving hospital. Accordingly, current regulations at 42 CFR 413.79(h)(2), which we do not believe need modification, state that a hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following criteria: (i) The hospital is training additional residents from a hospital that closed on or after July 1, 1996; (ii) No later than 60 days after the hospital begins to train the residents, the hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.(bold emphasis added).

Comment: A commenter supported the proposed broadened definition of ''displaced resident'' and commented that with regard to the inclusion of residents who are matched, but have not yet started training at the program at the closing hospital, CMS should clarify that when it uses the term ''matched'' that it means not only residents who were matched through the National Resident Matching Program (NRMP) on Match Day, but also those residents who are offered positions through the Supplemental Offer and Acceptance Program (SOAP) in the days following the initial Match process.

Response: We included in our proposed definition of ''displaced resident'' individuals (such as medical students or would-be fellows) who matched into GME programs at the closing hospital or program but have not yet started training at the closing hospital or program. We did not specify a particular match, nor did we limit the types of matches that would be acceptable. We are clarifying that eligible displaced residents may include those who matched either through the National Resident Matching Program (NRMP) or Supplemental Offer and Acceptance Program (SOAP), and may even include residents and fellows who are accepted into an approved medical residency program external to one of the commonly used match platforms. In response to this comment, we are modifying the proposed regulations text at 42 CFR 413.79(h)(1)(iii)(C) to remove the word ''match'' and instead state a resident who ''is accepted into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program.''

Comment: A commenter wondered why CMS would continue to require use of social security numbers, albeit only the last 4 digits, of displaced residents to be included in temporary cap transfer agreements, when CMS could require use of the resident's National Provider Identification (NPI) number instead. The commenter noted that once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes, and that while not required initially, as soon as residents transmit any health data, such as write prescriptions, refer patients, or order tests for patients in claims transactions, or for faculty to bill for their services, they are considered covered health care providers and must have an NPI number.

Response: In the proposed rule (85 FR 32786), we proposed that rather than continue to require inclusion of each displaced resident's full social security number in the temporary cap adjustment request submitted to a receiving hospital's Medicare Administrative Contractor, we proposed to require the receiving hospital to include the names and only the last four digits of each displaced resident's social security number. As the commenter stated, NPIs are not required initially, and therefore, it is likely that many PGY1 residents, in addition to individuals who graduated medical school and have been accepted into a residency program at the closing program or hospital, but have not yet started training at the closing program or hospital, would not yet have an NPI. Therefore, they could not be tracked by the MACs in the temporary cap transfer agreements with NPIs. As a compromise, we are modifying our proposal to require inclusion of either—(1) the last 4 digits of the social security number of a displaced resident; or (2) the NPI of the displaced resident, in the receiving hospital's letter to its MAC requesting the temporary increase in its IME and DGME FTE resident caps.

Comment: A commenter questioned CMS's policy about providing pass-through funding for pharmacy residents displaced by hospital closure.

Response: This comment is beyond the scope of the proposals in the proposed rule; therefore, we are not addressing this comment at this time.

We are finalizing our proposed policy with slight modification with regard to which residents can be considered ''displaced'' for Medicare temporary FTE resident cap transfer purposes in the situation where a hospital announces publicly that it is closing, and/or that it is closing a residency program(s). Specifically, we are finalizing the addition of the definition of ''displaced resident'' in new 42 CFR 413.79(h)(1)(iii) to read as set out in the regulatory text of this document, but at 42 CFR 413.79(h)(1)(iii)(C), we are removing the word ''match'' and instead stating a resident who ''is accepted into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program.'' In addition, we are finalizing our proposal with modification that to apply for the temporary increase in the IME and DGME FTE resident caps, the receiving hospital would have to submit a letter to its Medicare Administrative Contractor no later than 60 days after beginning to train the displaced residents, and must include in the letter either— (1) the last 4 digits of the social security number of the displaced resident; or (2) the NPI of the displaced resident.

Current IME regulations at 42 CFR 412.105(f)(1)(ix) link to the direct GME regulations at 42 CFR 413.79(h), so this regulation change would apply to the IME FTE cap transfers for displaced residents as well. In order to fully coordinate these IME regulations with the new definition of ''displaced resident,'' we are finalizing our proposal to slightly modify the regulations at 42 CFR 412.105(f)(1)(ix) to add the word ''displaced'' to describe residents added by a receiving hospital due to a hospital or program closure.

O. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed in this final rule). Section 15003 also required that, no later than 120 days after enactment of Public Law 114–255, the Secretary had to issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period, so long as the maximum number of 30 hospitals stipulated by Public Law 114–148 was not exceeded. In this final rule, we are providing a description of the provisions of section 15003 of Public Law 114–255, our final policies for implementation, and the finalized budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255. We note that the periods of participation for a number of the hospitals selected prior to the extension period authorized by Public Law 114–255 will have ended by the close of FY 2021, and that the budget neutrality methodology for this upcoming fiscal year will take into account the schedule of end dates.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A of Public Law 108–173 required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during the 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30. We refer readers to previous final rules for a summary of the selection and participation of these hospitals. Starting from December 2014 and extending through December 2016, the 21 hospitals that were still participating in the demonstration ended their scheduled periods of performance on a rolling basis, respectively, according to the end dates of the hospitals' cost report periods.

3. Provisions of the 21st Century Cures Act (Pub. L. 114–255) and Finalized Policies for Implementation

a. Statutory Provisions

As stated earlier, section 15003 of Public Law 114–255 further amended section 410A of Public Law 108–173 to require the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by Public Law 111–148), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Thus, the Secretary is required to conduct the demonstration for an additional 5-year period. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation. Furthermore, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals that are not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014,

in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In addition, section 15003 of Public Law 114–255 amended section 410A of Public Law 108–173 to add paragraph (g)(6)(A) which requires that the Secretary issue a solicitation for applications no later than 120 days after enactment of paragraph (g)(6) to select additional rural community hospitals located in any State to participate in the demonstration program for the second 5 years of the 10-year extension period, without exceeding the maximum number of hospitals (that is, 30) permitted under section 410A(g)(3) of Public Law 108–173 (as amended by Pub. L. 111–148). Section 410A(g)(6)(B) of the Act provides that, in determining which hospitals submitting an application pursuant to this solicitation are to be selected for participation in the demonstration, the Secretary must give priority to rural community hospitals located in one of the 20 States with the lowest population densities, as determined using the 2015 Statistical Abstract of the United States. The Secretary may also consider closures of hospitals located in rural areas in the State in which an applicant hospital is located during the 5-year period immediately preceding the date of enactment of Public Law 114–255 (December 13, 2016), as well as the population density of the State in which the rural community hospital is located.

(b) Terms of Participation for the Extension Period Authorized by Public Law 114–255

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and payment for services provided under the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Public Law 114–255) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 elected to continue in the second 5-year extension period for the full second 5-year extension period. (Of the four hospitals that did not elect to continue participating, three hospitals converted to CAH status during the time period of the second 5-year extension period). Therefore, the 5-year period of performance for each of these hospitals started on dates beginning May 1, 2015 and extending through January 1, 2017. On November 20, 2017, we announced that, as a result of the solicitation issued earlier in the year responding to the requirement in Public Law 114–255, 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (Hereafter, these two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost-reporting period on or after October 1, 2017. One of the hospitals selected from the solicitation in 2017 withdrew from the demonstration program prior to beginning participation in the demonstration on July 1, 2018. In addition, one of the previously participating hospitals closed effective January 2019, and another withdrew effective October 1, 2019. Therefore, 27 hospitals were participating in the demonstration as of this date—15 previously participating and 12 newly participating. For four of the previously participating hospitals, this 5-year period of participation will end during FY 2020; while one of the previously participating hospitals, scheduled to end in 2021, chose in February of this past year to withdraw effective September 2019. Therefore, the budget neutrality calculations in this final rule are based on 22 hospitals. For seven of the remaining 10 hospitals among the original group, participation will end during FY 2021, with participation ending for the other three on December 31, 2021. The newly participating hospitals are all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, made it extremely unlikely that this demonstration program could be held to budget neutrality under the methodology normally used to calculate it—that is, cost-based payments to participating small rural hospitals were likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. In addition, a rural community hospital's participation in this demonstration program would be unlikely to yield benefits to the participants if budget neutrality were to be implemented by reducing other payments for these same hospitals. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. Methodology Used in Previous Final Rules for Periods Prior to the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We note that we have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

(1) General Approach

We finalized our budget neutrality methodology for periods of participation under the second 5 years of the 10-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in this rule, as well as in the FY 2019 and FY 2020 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, and 84 FR19452 and 42421, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In these proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by Public Law 114–255.

- We included a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In the FY 2020 IPPS final rule, we included an estimate of the costs of the demonstration for FY 2020 for 28 hospitals.
- Similar to previous years, we continued to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that decided to participate in the second 5 years of the 10-year extension period, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the first 5-year extension period. In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). In the FY 2020 final rule, we included the difference between the amount determined for the cost of the demonstration in each of FYs 2014 and 2015 and the estimated amount included in the budget neutrality offset in the final rule for each of these respective fiscal years. For FY 2016 and subsequent years we will use finalized cost reports when available that detail the actual costs of the demonstration for each of these fiscal years and incorporate these amounts into the budget neutrality calculation.

(2) Methodology for Estimating Demonstration Costs for FY 2021

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2021. Noting again that four of the previously participating hospitals will end their participation during FY 2020, we are conducting this estimate for FY 2021 on the basis of the 22 hospitals that will participate during that fiscal year. The methodology for calculating this amount for FY 2021 proceeds according to the following steps:

Step 1: For each of these 22 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is that with cost report period end date in CY 2018. We note that among the seven hospitals that are scheduled to end participation during FY 2021, four will end prior to September 30, 2021. Therefore, consistent with previous practice, we prorate the cost amounts for these hospitals by the fraction of total months in the demonstration period of participation that fall within FY 2021 out of the total of 12 months in the fiscal year. For example, for a hospital withe period of performance ending June 30, 2021, this prorating factor is 0.75. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including

swing beds, across the total 22 hospitals participating during FY 2021.

Then, we multiply this amount by the FYs 2019, 2020 and 2021 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. (We are using the final market basket percentage increase for FY 2021, which can be found at section IV.B. of the preamble to this final rule). The result for the 22 participating hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2021.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2019 through 2021 to the applicable estimated reasonable cost amount (previously described) in order to model the estimated FY 2021 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2021 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. (Also, similar to step 1, we are prorating the amounts for hospitals whose period of participation ends prior to the end of FY 2021 by the fraction of total months in the demonstration period of participation for the hospital that fall within FY 2021 out of the total of 12 months in the fiscal year). We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2019, 2020 and 2021 IPPS applicable percentage increases. (Again, for FY 2021, we are using the final applicable percentage increase, per section IV.B. of the preamble of this final rule). This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 22 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2021.

For this final rule, the resulting amount is $39,825,670, which we are incorporating into the budget neutrality offset adjustment for FY 2021. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. We noted in the proposed rule that if updated data become available prior to the final rule, we would use them as appropriate to estimate the costs for the demonstration program for FY 2021 in accordance with our methodology for determining the budget neutrality estimate). Accordingly, we have revised the update factors from the proposed rule to indicate those presently finalized; and, in addition, accounted for the withdrawal of one hospital.

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2015 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

In the proposed rule, we stated that if finalized cost reports for the entire set of hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016 were available, we would include in the final budget neutrality offset amount for FY 2021 the difference between the actual cost as determined from these cost reports and the estimated amount identified in the final rule for FY 2016 At this point, however, not all cost reports have been finalized for the 18 hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016. Therefore, we will not be able to incorporate this amount in this final rule, but, instead, plan to address accordingly in the FY 2022 IPPS/LTCH PPS proposed and final rules.

(4) Total Budget Neutrality Offset Amount for FY 2020

Therefore, for this FY 2021 IPPS/LTCH PPS final rule, the budget neutrality offset amount for FY 2021 is based on the amount determined under section X.4.c.(2). of the preamble of this final rule, representing the difference applicable to FY 2021 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to the 22 hospitals participating in the fiscal year for covered inpatient hospital services and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $39,825,670.

Comment: A commenter expressed support for the continuation of the program, but stated, that as a demonstration, the program does not offer long-term financial sustainability needed to maintain health care access in rural areas.

Response: We appreciate the comment. We have conducted the demonstration program in accordance with Congressional mandates.

P. Market-Based MS–DRG Relative Weight Data Collection and Potential Change in Methodology for Calculating MS–DRG Relative Weights

1. Overview

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule, on October 12, 2017, President Trump issued Executive Order (E.O.) 13813 on *Promoting Healthcare Choice and Competition Across the United States.* E.O. 13813 directs the administration, to the extent consistent with law, to facilitate, ''the development and operation of a healthcare system that provides high-quality care at affordable prices for the American people,'' by increasing consumer choice and promoting competition in healthcare markets and by removing and revising government regulation.

As a result of E.O. 13813, the Secretary published a report entitled, ''Reforming America's Healthcare System Through Choice and Competition,'' which recognized the importance of price transparency in bringing down the cost of healthcare (for more information regarding this report, we refer readers to: *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf*). Building on the importance of transparency in healthcare pricing, in accordance with the President's E.O. on *Improving Price*

and Quality Transparency in American Healthcare to Put Patients First (issued on June 24, 2019), we proposed in the CY 2020 Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS/ASC PPS) proposed rule to establish requirements for all hospitals in the United States to make available to the public their standard charges for the items and services they provide, including their payer-specific negotiated charges for all of their items and services, and a more consumer-friendly display of their payer-specific negotiated charges for certain selected shoppable services (84 FR 39571). In the CY 2020 OPPS/ASC PPS, Price Transparency Requirements for Hospitals to Make Standard Charges Public final rule (CMS–1717–F2, referred to herein as the Hospital Price Transparency final rule) (84 FR 65538), we finalized these requirements for all hospitals in the United States for making hospital standard charges available to the public, beginning January 1, 2021, as well as an enforcement scheme to enforce those requirements. We also finalized that the term ''standard charge'' means the regular rate established by the hospital for an item or service provided to a specific group of paying patient, and includes all of the following as defined in our regulations at 45 CFR 180.20: (1) Gross charge; (2) payer-specific negotiated charge; (3) de-identified minimum negotiated charge; (4) de-identified maximum negotiated charge; and (5) discounted cash price.

There are three broad types of hospital rates, depending on the patient and payer: (1) Medicaid and Medicare fee for service (FFS) rates; (2) negotiated rates with private issuers or health plans; and (3) uninsured or self-pay, as discussed in the Hospital Price Transparency final rule (84 FR 65538).

Medicaid FFS rates are dictated by each State and tend to be at the lower end of market rates. Medicare FFS rates are determined by CMS and those rates tend to be higher than Medicaid rates within a state. Privately negotiated rates vary with the competitive structure of the geographic market and usually tend to be somewhat higher than Medicare rates, but in some areas of the country the two sets of rates tend to converge. Uninsured or self-pay patient rates are often the same as chargemaster [441] (gross) rates, which are usually highly inflated in order to secure higher payments from Medicare and private payers.[442]

Under the old hospital reimbursement system, the more services a hospital provided and longer a patient's stay, the greater the reimbursement. Congress, recognizing that the reimbursement system created disincentives to provide efficient care, enacted in 1983 a prospective payment system. The primary objective of the prospective payment system is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries.

To partly compensate hospitals for certain overly costly hospitalizations, hospitals may receive an ''outlier'' payment which is based on the hospital's billed charges, adjusted to cost, in comparison to the payment that would otherwise be received and an outlier threshold (see 42 CFR 412.84). To determine whether an individual case would qualify for an outlier payment, the hospital's cost-to-charge ratio (CCR) is applied to the covered charges to estimate the costs of the case. In the late 1990s, many hospitals began manipulating or gaming that ratio to make it easier to qualify for outlier payments. The larger the charges, the smaller the ratio, but it takes time for the ratio to be updated (unless the hospital directly updated their cost-to-charge ratio with the MAC). Thus, by way of example, if a hospital had a cost-to-charge ratio 1 to 5, or 20 percent, then a pill which cost the hospital $1 to purchase might be billed to a patient at $5. However, if the hospital doubled the charge to the patient to $10, the corresponding change in its ratio would take time to be updated. Its costs might look like $2 instead of $1 in the interim. Rule changes such as those made in the IPPS/LTCH PPS Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Final Rule (June 9, 2003; 68 FR 34497 through 34504), we established policies related to updating CCRs and the reconciliation of outlier payments, which reduced such manipulation (for more information regarding these changes we refer readers to: *https://www.govinfo.gov/content/pkg/FR-2003-06-09/pdf/03-14492.pdf*). Nevertheless, some hospitals' charges do not reflect market rates. Hospital bills that are generated off these chargemaster rates can be inherently unreasonable when judged against prevailing market rates.

Recognizing that chargemaster (gross) rates rarely reflect the true market costs, we believe that by reducing our reliance on the hospital chargemaster, we can adjust Medicare payment rates so that they reflect the relative market value for inpatient items and services. Additionally, we have received public feedback that the Medicare program's use of hospital gross charges for some payments in ratesetting has served as the most significant barrier to hospitals' efforts to rebase their chargemasters. These stakeholders argued that this Medicare payment process serves as a barrier for rebasing changes, because any reduction in charges requires coordination with Medicare, Medicaid and commercial health plans so that any changes occur in a revenue-neutral manner to the hospital. We continue to believe that our existing administrative mechanisms for hospitals to voluntarily lower their charges adequately address these commenters' concerns. Specifically, if a hospital is planning on voluntarily lowering its charges, it can request a CCR change pursuant to 42 CFR 412.84(i)(1) and as also discussed in prior rulemaking (84 FR 42630). Nevertheless, we agree in general that a decreased reliance on hospital chargemasters in Medicare payment would be desirable, if an appropriate alternative mechanism exists and is permitted by statute.

Furthermore, the goal of reducing the Medicare program's reliance on the chargemaster and adopting payment strategies that are more reflective of the commercial insurance market was showcased within E.O. 13890 on *Protecting and Improving Medicare for Our Nation's Seniors,* which President Trump issued on October 3, 2019. The E.O. described the market benefits provided under the Medicare Advantage program as providing, ''efficient and value-based care through choice and private competition, and has improved aspects of the Medicare program that previously failed seniors.'' E.O. 13890 then directed the Medicare program to adopt and implement those market-based recommendations developed pursuant to Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States), and published in the Administration's report on, ''Reforming America's Healthcare System Through Choice and Competition.'' Furthermore, E.O. 13890 directed HHS to identify,

[441] CMS currently refers to chargemasters as a Charge Description Master or CDM, which means the list of all individual items and services maintained by a hospital for which the hospital has established a charge.

[442] Richman BD, et al. Battling the Chargemaster: A Simple Remedy to Balance Billing for Unavoidable Out-of-Network Care. Am J Manag Care. 2017;23(4):e100–e105 Available at: *https://www.ajmc.com/journals/issue/2017/2017-vol23-n4/battling-the-chargemaster-a-simple-remedy-to-balance-billing-for-unavoidable-out-of-network-care.*

''approaches to modify Medicare FFS payments to more closely reflect the prices paid for services in MA and the commercial insurance market, to encourage more robust price competition, and otherwise to inject market pricing into Medicare FFS reimbursement.'' E.O. 13890 directed the Secretary, in consultation with other partners, to produce a report with approaches to achieve the goal of establishing more market-based pricing within Medicare FFS reimbursements within 180 days of the E.O.'s issuance. (For additional information on E.O. 13890, we refer readers to: *https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors*.) (For more information on E.O. 13813, we direct readers to: *https://www.federalregister.gov/documents/2017/10/17/2017-22677/promoting-healthcare-choice-and-competition-across-the-united-states*.)

In order to reduce the Medicare program's reliance on the hospital chargemaster, thereby advancing the critical goals of EOs 13813 and 13890, and to support the development of a market-based approach to payment under the Medicare FFS system, we proposed that hospitals would be required to report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021, to be used in a potential change to the methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing.

As described further in section IV.P.2.c. of the preamble of this final rule, we specifically proposed that hospitals would report on the Medicare cost report two median payer-specific negotiated charges ''by MS–DRG.'' For a third party payer that uses the same MS–DRG patient classification system used by Medicare, the payer-specific negotiated charges that the hospital uses to calculate the median by MS–DRG would be the payer-specific negotiated charges the hospital negotiated with that third party payer for the MS–DRG to which the patient discharge was classified. However, we recognize that not all third party payers use the MS–DRG patient classification system. For those third party payers that do not, the payer-specific negotiated charges they negotiate with hospitals would be based on the system used by that third party payer, such as per diem rates or APR–DRGs. In that case, the hospital would determine and report the median payer-specific negotiated charges by MS–DRG using its payer-specific negotiated charges for the same or similar package of services that can be crosswalked to an MS–DRG. For simplicity, we refer to this data collection herein as collecting the median payer-specific negotiated charge by MS–DRG. We believed that the use of these data in the MS–DRG relative weight setting methodology would represent a significant and important step in reducing the Medicare program's reliance on hospital chargemasters, and would better reflect relative market-based pricing in Medicare FFS inpatient reimbursements.

Specifically, we proposed that hospitals would report on the Medicare cost report: (1) The median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations (also referred to as MA organizations) payers, by MS–DRG; and (2) the median payer-specific negotiated charge the hospital has negotiated with all of its third party payers, which would include MA organizations, by MS–DRG. The market-based rate information we proposed to collect on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, as described previously, for a hospital's MA organization payers and all of its third party payers. The payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency final rule (84 FR 65524) that can be crosswalked to an MS–DRG. We stated that if we finalized this market-based data collection proposal, hospitals would use the payer-specific negotiated charge data that they would be required to make public, as a result of the Hospital Price Transparency final rule, to then calculate the median payer-specific negotiated charges (as described further in section IV.P.2.c. of this final rule) to report on the Medicare cost report. We believed that because hospitals are already required to publicly report payer-specific negotiated charges, in accordance with the Hospital Price Transparency final rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

We also sought comment on a potential change to the methodology for calculating the IPPS MS–DRG relative weights to incorporate this market-based rate information, beginning in FY 2024, which we stated that we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. As described in greater detail in section IV.P.d. of the preamble of this final rule, this methodology would involve using hospitals' reported median payer-specific negotiated charges to develop market-based IPPS payments to reflect the relative hospital resources used to provide inpatient services to patients. The use of payer-specific negotiated charges would replace the current use of gross charges that are reflected on a hospital's chargemaster and cost information from Medicare cost reports for the development of the IPPS MS–DRG relative weights. CMS requested comment on the use of hospitals' reported median payer-specific negotiated charge data, which would be calculated using a subset of the payer-specific negotiated charges that, starting January 1, 2021, hospitals are required to make public under 45 CFR part 180. As proposed, the median payer-specific negotiated charges calculated and submitted by hospitals for each MS–DRG would be limited to charges hospitals have negotiated with: (1) MA organizations; and (2) third party payers, including MA organizations. As noted previously, we believed the use of payer-specific negotiated charge data in the MS–DRG relative weight setting methodology would help reduce the Medicare program's reliance on hospital chargemasters, and would reflect relative market-based pricing in Medicare FFS inpatient reimbursements.

2. Market-Based MS–DRG Relative Weight Estimation

a. Overview

Section 1886(d)(4)(A) of the Act states that the Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. Section 1886(d)(4)(B) of the Act states that for each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. For the reasons discussed, we believed the use of market-based data, to be collected on the Medicare cost report, may support the development of an appropriate market-based approach to payment under the Medicare FFS system by incorporating such data into the estimation of the relative hospital resources used with respect to discharges classified within a single MS–DRG compared to discharges

classified within other MS–DRGs, as required by statute.

As stated in the proposed rule, we currently use a cost-based methodology to estimate an appropriate weight for each MS–DRG. These weights reflect the relative hospital resources used with respect to discharges classified within that MS–DRG compared to discharges classified within other MS–DRGs. The current cost-based methodology primarily uses hospital charges from the MedPAR claims data and cost report data from the Healthcare Cost Report Information System (HCRIS) to establish the MS–DRG relative weights (the collection of cost report data is authorized under OMB 0938–0050, which is used to produce both files). (We refer readers to section II.E. of this final rule for the discussion of the finalized methodology used to recalibrate the FY 2021 MS–DRG cost-based relative weights.) This cost-based methodology was originally proposed and finalized with revisions in the FY 2007 IPPS rulemaking (71 FR 24006 through 24011 and 71 FR 47881 through 47898); it has since been modified in subsequent IPPS rulemaking. Prior to the FY 2007 IPPS rulemaking, we used a charge-based DRG relative weight methodology.

Hospitals are already required to make their payer-specific negotiated charge data for service packages publicly available under the Hospital Price Transparency final rule (45 CFR 180.20). As discussed in the proposed rule, consistent with the desire to reduce the Medicare program's reliance on the hospital chargemaster, as well as to inject market pricing into Medicare FFS reimbursement, we believe it is again appropriate to reconsider our current approach to calculating the MS–DRG relative weights. For these reasons, we have reexamined the need to continue to use the charges on IPPS hospital claims, in conjunction with charge and cost data on hospital cost reports, to estimate the MS–DRG relative weights. In particular, we stated that we were considering whether the payer-specific negotiated charges by MS–DRG for MA organizations, or alternatively the payer-specific negotiated charges by MS–DRG for all third party payers (we note that this would include MA organization data), or some other approach that would reflect relative market-based charges by MS–DRG, could provide an appropriate basis for estimating the relative hospital resources used with respect to discharges classified within a single MS–DRG compared to discharges classified within other MS–DRGs, as required by statute.

b. Research Comparing Medicare, Medicare Advantage Organization, and Commercial Payment Rates

As an initial matter, as discussed in the proposed rule, we focused on the charges negotiated between hospitals and MA organizations given that MA plans are often paying for the same units and types of services as fee-for-service (FFS) Medicare. As part of our consideration of this issue, we looked to existing public research on the relationship between Medicare FFS inpatient payment rates and the payment rates negotiated between hospitals and MA organizations. Berenson et al.[443] surveyed senior hospital and health plan executives and found that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less. Respondents broadly identified three primary reasons for near payment equivalence: statutory and regulatory provisions that limit out-of-network payments to traditional Medicare rates, de facto budget constraints that MA plans face because of the need to compete with traditional Medicare and other MA plans, and a market equilibrium that permits relatively lower MA rates as long as commercial rates remain well above the traditional Medicare rates.

We next researched empirically based comparisons of Medicare FFS rates, MA organization rates, and rates of other commercial payers. Baker et al.[444] used data from Medicare and the Health Care Cost Institute (HCCI) to identify the prices paid for hospital services by FFS Medicare, MA plans, and commercial insurers in 2009 and 2012. They calculated the average price per admission, and its trend over time, in each of the three types of insurance for fixed baskets of hospital admissions across metropolitan areas. After accounting for differences in hospital networks, geographic areas, and case-mix between MA and FFS Medicare, they found that MA plans paid 5.6 percent less for hospital services compared to FFS Medicare. For the time period studied, the authors suggest that at least one channel through which MA plans paid lower prices was by obtaining greater discounts on types of FFS Medicare admissions that were known to have very short lengths-of-stay. They also found that the rates paid by commercial plans were much higher than those of either MA or FFS Medicare, and growing. At least some of this difference they indicated came from the much higher prices that commercial plans paid for profitable service lines.

Maeda and Nelson[445] also analyzed data from the HCCI in their research. They compared the hospital prices paid by MA organizations and commercial plans with Medicare FFS prices using 2013 claims from the HCCI. The HCCI claims were used to calculate hospital prices for private insurers, and Medicare's payment rules were used to estimate Medicare FFS prices. The authors focused on stays at acute care hospitals in metropolitan statistical areas (MSAs). They found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. The authors considered their results generally consistent with the Baker et al. study findings in that hospital payments by MA plans were much more similar to Medicare FFS levels than they were to commercial payment levels, although they noted that they used slightly different methods to calculate Medicare FFS prices.

In their study, Maeda and Nelson also examined whether the ratio of MA prices to FFS prices varied across DRGs to assess whether there were certain DRGs for which MA plans tended to pay more or less than FFS. They ranked the ratio of MA prices to FFS prices and adjusted for outlier payments. The authors state that they found that, ''there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS.'' For example, for the time period in question, on average, MA plans paid 129 percent more than FFS for rehabilitation stays (DRG 945), 33 percent more for depressive neuroses (DRG 881), and 27 percent more for stays related to psychoses (DRG 885). But MA plans paid an average of 9 percent less than FFS for stays related to pathological fractures (DRG 542) and wound debridement and skin graft (DRG 464) (see Online Appendix Table 5 from their study). The authors state these results suggest that there may be certain services where MA plans pay more than FFS possibly because the FFS rates for

[443] Berenson R.A., Sunshine J.H., Helms D., Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. *Health Aff (Millwood).* 2015;34(8):1289–1295.

[444] Baker L.C., Bundorf M.K., Devlin A.M., Kessler D.P. Medicare Advantage plans pay less than traditional Medicare pays. *Health Aff (Millwood).* 2016;35(8):1444–1451.

[445] Maeda J.L.K., Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? *The Journal of Health Care Organization, Provision, and Financing.* 2018;55(1–8).

those services are too low, but that there may be other services where MA plans pay less than FFS possibly because the FFS rates for those DRGs are too high (Maeda, Nelson, 2018 p. 5).

Taken as a whole, we continue to believe this body of research suggests that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, and payer-specific charges negotiated between hospitals and other commercial payers are generally not as well-correlated with Medicare IPPS payment rates. With respect to either type of payer-specific negotiated charges, there may be instances where those negotiated charges may reflect the relative hospital resources used within an MS–DRG differently than our current cost-based methodology.

Considering the public availability of payer-specific negotiated charges starting in CY 2021 and the desire to reduce the Medicare program's reliance on the hospital chargemaster, we believed we could adjust the methodology for calculating the MS–DRG relative weights to reflect a more market-based approach under our authority under sections 1886(d)(4)(A), 1886(d)(4)(B) and 1886(d)(4)(C) of the Act.

c. Market-Based Data Collection

For the reasons discussed, in order to support the development of a relative market-based payment methodology under the IPPS, as well as satisfy E.O.s 13813 and E.O. 13890 by reducing our reliance on the hospital chargemaster, we proposed to collect market-based payment rate information on Medicare cost reports beginning with cost reporting periods ending on or after January 1, 2021. Sections 1815(a) and 1833(e) of the Act provide that no Medicare payments will be made to a provider unless it has furnished the information, as may be requested by the Secretary, to determine the amount of payments due the provider under the Medicare program. We require that providers follow reasonable cost principles under section 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, we define adequate cost data and require cost reports from providers on an annual basis. As previously discussed, the collection of this market-based data on the Medicare cost report would allow for the adoption of market-based strategies in determining Medicare FFS payments and would reduce our reliance on the hospital chargemaster for ratesetting purposes, in particular for purposes of estimating the appropriate weighting factor to reflect the relative hospital resources used with respect to hospital discharges, as required under sections 1886(d)(4)(B) and 1886(d)(4)(C) of the Act.

First, we proposed to collect on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG. Second, we proposed to collect on the Medicare cost report the median payer-specific negotiated charge the hospital has negotiated with all of its third party payers, which would include MA organizations, by MS–DRG. We proposed to collect the median of the hospital payer-specific negotiated charges, because the median is a common measure of central tendency that is less influenced by outlier values. As described in more detail later in this section, we proposed to collect the hospital's median payer-specific negotiated charges by MS–DRG, which would be calculated using the payer-specific negotiated charge data for service packages that hospitals are required to make public under the Hospital Price Transparency final rule that can be cross-walked to an MS–DRG.

Medicare certified providers, such as Medicare certified hospitals, are required to submit an annual cost report to their Medicare Administrative Contractor (MAC). The Medicare cost report contains provider information such as facility characteristics, cost and charges by cost center, in total and for Medicare, Medicare settlement data, and financial statement data. The cost report must be submitted in a standard (ASCII) electronic cost report (ECR) format. CMS maintains the cost report data in the HCRIS dataset. The HCRIS data supports our reimbursement policymaking, congressional studies, legislative health care reimbursement initiatives, Medicare profit margin analysis, and relative weight updates. As such, every data point from hospital cost reports beginning on or after May 1, 2010 is reflected on the HCRIS dataset, and available for public access and use.

We stated in the proposed rule that accordingly, if we were to finalize this proposal to collect the proposed market-based information (specifically, the median payer-specific negotiated charges negotiated between a hospital and all its MA organization payers, by MS–DRG and the median payer-specific negotiated charges negotiated between a hospital and all its third party payers, by MS–DRG) on the cost report, that this data would become publicly accessible on the HCRIS dataset in a de-identified manner and would be usable for analysis by third parties. The data would, by definition, be de-identified since we proposed that the hospital calculate the median rate (that is, the specific rate that is negotiated between a hospital and a specific third party payer for an MS–DRG would not be reported and need to be de-identified). For more information or to obtain HCRIS data we refer readers to: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.html.*

A payer-specific negotiated charge is the charge that a hospital has negotiated with a third party payer for an item or service provided by the hospital. We noted that the definition of third party payer, for the purposes of this rule and data collection proposal, includes MA organizations. As described later in this section, we proposed that the two median payer-specific negotiated charges by MS–DRG that hospitals would be required to report on the Medicare cost report for cost reporting periods ending on or after January 1, 2021, would be calculated using the payer-specific negotiated charges for service packages that hospitals are required to make publicly available under the Hospital Price Transparency final rule that can be cross-walked to a MS–DRG.

The Hospital Price Transparency final rule required that hospitals make publicly available via the internet their standard charges (including, as applicable, gross charges, payer-specific negotiated charges, de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices) in two different ways: (1) A single machine-readable file containing a list of standard charges for all items and services provided by the hospital that complies with requirements described in 45 CFR 180.50; and (2) a consumer-friendly list of standard charges for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services, that complies with requirements described in 45 CFR 180.60. For purposes of this rule and data collection proposal, we proposed that hospitals would calculate the median payer-specific negotiated charge by MS–DRG using the payer-specific negotiated charge data by MS–DRG from the single machine-readable file for all items and services (as required by the Hospital Price Transparency final rule) and not the

version of payer-specific negotiated charge data included within the file for public production, in a consumer-friendly manner, of CMS-specified and hospital-selected shoppable services.

We proposed the following methodology for how each hospital would calculate its median payer-specific negotiated charge for MA organizations by MS–DRG and its median payer-specific negotiated charge for all third party payers by MS–DRG. We proposed to collect this data for purposes of incorporating market-based rate information into the IPPS payment methodologies. We stated that the median payer-specific negotiated charge data would be reported by MS–DRG for consistency with the grouping system that we currently use to classify inpatient hospital discharges under section 1886(d)(4)(A) of the Act. Therefore, as referenced previously, hospitals would report the payer-specific negotiated charges by MS–DRG and not by another DRG classification system.

To determine the median payer-specific negotiated charge for MA organizations for a given MS–DRG, a hospital would list, by MS–DRG, each discharge in its cost reporting period that was paid for by an MA organization, and the corresponding payer-specific negotiated charge that was negotiated as payment for items and services provided for that discharge. The median payer-specific negotiated charge for payers that are MA organizations, for that MS–DRG, would be the median payer-specific negotiated charge in that list of discharges.

A simplified example for the purpose of illustrating this process is as follows. Hospital A has negotiated four different payer-specific charges with four MA organizations for hypothetical MS–DRG 123. The four payer-specific negotiated charges are $7,300, $7,400, $7,600, and $7,700. In its cost reporting period, Hospital A had 3 discharges for which $7,300 was the basis for payment for the items and services provided for that discharge, 2 discharges for which $7,400 was the basis for payment for the items and services provided for that discharge, 1 discharge for which $7,600 was the basis for payment for the items and services provided for that discharge, and 1 discharge for which $7,700 was the basis for payment for the items and services provided for that discharge. Therefore, for Hospital A, the payer-specific negotiated charges for its list of discharges paid for by MA organizations in its cost reporting period for MS–DRG 123 is $7,300, $7,300, $7,300, $7,400, $7,400, $7,600, and $7,700. The median of this list is $7,400. Hospital A's median payer-specific negotiated charge for MS–DRG 123 for payers that are MA organizations would be $7,400.

The methodology we proposed for how each hospital would calculate its median payer-specific negotiated charge for a given MS–DRG for all third party payers, including MA organizations, is the same as the process outlined previously.

For purposes of this calculation, we proposed to define the term, ''payer-specific negotiated charge'' as the charge that a hospital has negotiated with a third party payer for an item or service. We proposed to use this definition of the payer-specific negotiated charge, because it would capture the charges that are negotiated between hospitals and third party payers, including MA organizations, and can provide the data needed to evaluate the use of market-based information for payment purposes within the MS–DRG relative weight calculation. For consistency, the definition of payer-specific negotiated charge that we proposed to use for purposes of this proposal is the same definition of ''payer-specific negotiated charge'' that we finalized for purposes of our requirements for hospitals to make their standard charges available to the public under the Hospital Price Transparency final rule. We also proposed to define, ''items and services'' as all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission for which the hospital has established a standard charge. An MS–DRG, as established by CMS under the MS–DRG classification system, is a type of service package consisting of items and services based on patient diagnosis and other characteristics. We proposed this definition of items and services, because we believed it captured the types of items and services, including service packages, that a hospital would use to calculate and report the median payer-specific negotiated charge for each MS–DRG to support the use of market-based rate information by MS–DRG within the MS–DRG relative weight calculation. This proposed definition is also the same definition of items and services that we finalized for purposes of our requirements for hospitals to make their standard charges available to the public under the Hospital Price Transparency final rule, except that we have omitted the reference to outpatient department visits, because we would not require hospitals to calculate the median of their payer-specific negotiated charges for items and services provided in the hospital outpatient setting under our proposal.

For purposes of this calculation, an MA organization is defined in 42 CFR 422.2; namely, an MA organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.

For purposes of this calculation, we proposed to define third party payer as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service. As the reference to ''third party'' suggests, this definition excludes an individual who pays for a healthcare item or service that he or she receives (such as self-pay patients). We proposed to use this definition of third party payer, because these are the types of entities that contract with hospitals to reimburse for services on behalf of patients. This definition is also the definition of third party payer finalized in the Hospital Price Transparency final rule.

We invited public comment on the proposed definitions of payer-specific negotiated charge, items and services, and third party payer. As discussed previously, we recognized that hospitals may negotiate rates in several ways and under different circumstances. For example, hospitals may negotiate rates with third party payers as a percent discount off chargemaster rates, on a per diem basis, or by MS–DRG or other similar DRG system. We also recognized that there may be hospitals that do not negotiate charges for service packages by MS–DRG or for service packages that may be crosswalked to an MS–DRG. Therefore, we sought comment on whether hospitals' median payer-specific negotiated charges across all types of payment methodologies should be included in the determination of the median payer-specific negotiated charge for the conditions and procedures that are classified under the MS–DRG system and if so, how the proposed definitions should be modified to encompass these other types of negotiation strategies or methodologies. We also sought comment on the appropriateness of using MS–DRGs or MS–DRG equivalents for this methodology, as well as whether we should potentially collect this information for payers that use MS–DRGs separately from payers that use other DRG systems. Furthermore, we sought comment on alternatives that would capture market-based information for the potential use in Medicare FFS payments. We also

welcomed comments and suggested refinements to our proposed definitions, as well as market-based alternatives that we should consider when identifying the market-based information that reflects the charges that a hospital negotiates for a specific MS–DRG.

In order to address some of the issues noted previously, as an alternative, we considered requiring hospitals to submit a median negotiated reimbursement amount across all MA organizations and across all third party payers (including MA organizations) by MS–DRG (or by an MS–DRG equivalent, such as APR–DRG). Under this alternative approach, we stated we would define the ''negotiated reimbursement amount'' as the amount the hospital received as payment for the services rendered for a patient discharge, as classified under the MS–DRG system, and for which the hospital negotiated payment with a third party payer, including a MA organization, for hospital cost reporting periods ending on or after January 1, 2021. Hospitals would be required to determine and submit the median negotiated reimbursement amount for—(1) MA organizations; and (2) all third party payers, which includes MA organizations.

For example, a hospital may negotiate a case rate (that is, a payer-specific negotiated charge) of $30,000 with Payer A for a major joint replacement paid under the APR–DRG system (equivalent to MS–DRG 470). The hospital and payer have agreed to a stop loss threshold of $150,000 and that the hospital will be reimbursed at 50 percent off the gross (chargemaster) rate for each dollar charged over the stop-loss amount. Additionally, the hospital would be reimbursed for 60 percent of the cost of the implanted hardware, an amount that, in some cases, may be variable depending on the type or style of hardware implanted. In this example, we stated that the hospital's payer-specific negotiated charge for a major joint replacement (MS–DRG 470 equivalent) is $30,000. However, we stated that the resulting payment per discharge would vary, depending upon factors such as whether the patient's course of treatment exceeded the agreed-upon stop loss amount and the cost of the hardware implant.

We considered this alternative, because the median of the ''negotiated reimbursement amount'' is an amount that may take into consideration the actual and final payment amounts received by hospitals from third party payers, and MA organizations, for care of individuals, as compared to a standard charge negotiated for a particular service package identified by MS–DRG. We requested comment on this alternative approach, which we believed may also provide a reasonable market-based estimate of the relative resources used to provide services for an MS–DRG, and may take into account the several ways that hospitals and third party payers negotiate charges.

We also sought comment on the relative burden of calculating and submitting a median negotiated reimbursement amount for MA organizations and for all other third party payers as compared to calculating and submitting the median payer-specific negotiated charge for MA organizations and median payer-specific negotiated charge for third party payers by MS–DRG payment system.

We proposed that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information. We noted that hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this proposed data collection. We recognized that Critical Access Hospitals (CAHs) may, in some instances, negotiate payment rates; however, because CAHs are not subsection (d) hospitals and are not paid on the basis of MS–DRGs, CAHs would be excluded from this proposed data collection requirement. We proposed that hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model, would be exempted from this data collection requirement during the performance period of the Model. Examples of subsection (d) hospitals that only receive non-negotiated payment rates include hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act or federally owned and operated facilities. We noted that this proposed data collection requirement would apply to a smaller subset of hospitals as compared to the public reporting requirements under the Hospital Price Transparency final rule.

We proposed that for cost reporting periods ending on or after January 1, 2021, a hospital would report on its cost report the median payer-specific negotiated charge for each MS–DRG for payers that are MA organizations, and the median payer-specific negotiated charge for each MS–DRG for all third party payers, which includes MA organizations. We stated that the required cost report reporting changes to accomplish this would be in more detail in the Information Collection Request approved under OMB No. 0938–0050.

We also proposed to amend 42 CFR 413.20(d)(3) to reflect this proposed requirement. Specifically, we proposed to amend 42 CFR 413.20(d)(3) to require hospitals to report the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations and for all third party payers on the Medicare cost report. We proposed to capture this proposed data collection requirement in regulation at the new paragraph 42 CFR 413.20(d)(3)(i)(B). This proposed requirement would be effective for cost reporting periods ending on or after January 1, 2021.

As described previously, we proposed to require hospitals to report on the Medicare cost report both the hospital's median payer specific negotiated charge by MS–DRG for all MA organizations and the hospital's median payer-specific negotiated charge by MS–DRG for all third party payers, which includes MA organizations, for cost reporting periods ending on or after January 1, 2021. We noted that we may also consider finalizing the collection of alternative market-based data, such as the median negotiated reimbursement amount as explained previously, or any refinements to the definition of median payer-specific negotiated charge, based on review of public comments. We stated that we were also considering a modification to the market based data collection proposal, to require only the reporting of the median payer-specific negotiated charge for MA organizations on the Medicare cost report. We invited public comments on our proposed data collection, as well as on these or other alternative data collections of payer-specific negotiated charges or other market-based information on the Medicare cost report, which we stated that we may consider finalizing in the FY 2021 IPPS/LTCH PPS final rule for cost reporting periods ending on or after January 1, 2021, after consideration of the comments received.

d. Market-Based MS–DRG Relative Weight Methodology

We also requested comments on a potential new market-based methodology for estimating the MS–DRG relative weights, beginning in FY 2024, which we stated we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. We described this potential new market-based methodology as based on the proposed median payer-specific negotiated charge information collected on the Medicare cost report. We stated that by implementing this potential new

market-based methodology beginning in FY 2024 it would allow for sufficient time, should we finalize our data collection proposal, for CMS to collect and evaluate the median payer-specific negotiated charge data submitted on hospital cost reports and provide the public with information regarding our analysis in future rulemaking. Specifically, we considered a methodology for estimating the MS–DRG relative weights using the median payer-specific negotiated charge for each MS–DRG for payers that are MA organizations, as described in this section. We further noted that the MA program provides efficient and value-based care to patients through choice and private competition. We believed that by using the median payer-specific negotiated charge for payers that are MA organizations within the MS–DRG relative weight calculation would allow for a more market-based approach to determining Medicare FFS reimbursement and reduce our reliance on the hospital chargemaster.

We also considered alternatives to this approach, such as the use of the median payer-specific negotiated charge for all third party payers (instead of the median payer-specific negotiated charge for all MA organizations), or other alternative collections of payer-specific negotiated charges or other market-based information such as a median negotiated reimbursement amount that a hospital negotiates with its MA organizations or third party payers (as described further in section IV.P.2.c of the preamble of this final rule), within the MS–DRG relative weight methodology. We also noted in the proposed rule that the same relative weight calculation described in this section would be used if an alternative to the median payer-specific negotiated charge was finalized to be collected on the Medicare cost report, as described in section IV.P.2.c. of the preamble of the proposed final rule.

We stated that the same relative weight calculation described in this section would be used if an alternative to the median payer-specific negotiated charge was finalized to be collected on the Medicare cost report, as described in section IV.P.2.c of the preamble of the proposed rule. We also invited public comment on this potential change to the relative weight methodology beginning in FY 2024 to use the median payer-specific negotiated charge for MA organizations, as well as the other potential alternative data collections as described in section IV.P.2.c of the preamble of this final rule, which we stated we may consider finalizing in the FY 2021 IPPS/LTCH PPS final rule. We also stated that if we were to finalize a change in the IPPS FY 2021 rulemaking to incorporate payer-specific negotiated charges within the MS–DRG relative weight methodology, effective for FY 2024, we were open to adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date. We also stated that should we finalize our data collection proposal, we would conduct further analysis based on the data received and provide an opportunity for public comment on that analysis, prior to the finalized effective date of any MS–DRG relative weight methodology change.

Below is a description of the steps for a MS–DRG relative weight methodology change using the payer-specific negotiated charge data, as described in IV.P.2.c of the proposed rule.

- *Step One:* Standardize the Median MA Organizations Payer-Specific Negotiated Charges

In order to make the median MA organization payer-specific negotiated charges from the cost reports more comparable among hospitals, we stated that we would standardize the median payer-specific negotiated charges by removing the effects of differences in area wage levels, and cost-of living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the current MS–DRG relative weight calculation for those effects. We sought comment on the appropriate standardization for the median MA organization payer-specific negotiated charges, and any differences that should be taken into account in standardizing the median payer-specific negotiated charges for all third party payers.

- *Step Two:* Create a Single Weighted Average Standardized Median MA Organization Payer-Specific Negotiated Charge by MS–DRG Across Hospitals

For each MS–DRG, we stated we would create a single weighted average across hospitals of the standardized median payer-specific negotiated charges. We stated we would weight the standardized payer-specific negotiated charge for each MS–DRG for each hospital using that hospital's Medicare transfer-adjusted case count for that MS–DRG, with transfer adjusted case counts calculated exactly the same way as under the current MS–DRG relative weight methodology (84 FR 42621). We believed that using the Medicare transfer-adjusted case counts would be a reasonable approach to combining the data across hospitals because it would reflect relative volume and transfer activity (that is, larger hospitals responsible for more discharges would be weighted more heavily in the calculation, hospitals that transfer more often would be weighted less heavily), however, we noted in the proposed rule that we may also consider alternative approaches, such as using the unadjusted Medicare case counts, or other alternative approaches based on the review of public comments. We sought comment on the most appropriate weighting factor for purposes of calculating a single weighted average standardized median MA organization payer-specific negotiated charge across hospitals.

- *Step Three:* Create a Single National Weighted Average Standardized Payer-Specific Negotiated Charge Across all MS–DRGs

We stated that we would create a single national weighted average across MS–DRGs of the results of Step Two, where the weights were the national Medicare transfer adjusted case counts by MS–DRG. We noted that if we used an alternative weighting factor to the Medicare transfer adjusted case counts in Step Two, as described previously, we would use that same alternative weighting factor here in Step Three.

- *Step Four:* Calculate the Market-Based Relative Weights

For each MS–DRG, we stated that the market-based relative weight would be calculated as the ratio of the single weighted average standardized median MA organization payer-specific negotiated charge for that MS–DRG across hospitals from Step Two to the single national weighted average standardized median MA organization payer-specific negotiated charge across all MS–DRGs from Step Three.

- *Step Five:* Normalize the Market-Based Relative Weights

We noted in the proposed rule that as under the current cost-based MS–DRG relative weight methodology, the market-based relative weights would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration. We stated that as under the current cost-based relative weight estimation methodology, the normalization adjustment is intended to help ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

We requested comments on this potential new market-based methodology for estimating the MS–DRG relative weights beginning in FY 2024, including comments on any suggested refinements to this potential methodology or alternative approaches,

which we stated we may consider adopting in the FY 2021 IPPS/LTCH final rule.

In the FY 2021 IPPS/LTCH proposed rule we noted that some stakeholders requested that we take a measured approach to any changes to adopting any market-based payment method for establishing Medicare IPPS reimbursements. We stated that we were therefore also interested in comments, on whether, if we were to adopt some form of a market-based approach to the MS–DRG relative weight calculation, we should, for some period of time, continue to estimate and publicly provide the MS–DRG relative weights as calculated using our current cost-based estimation methodology. We also expressed an interest in comments on whether we should provide a transition to any new market-based MS–DRG methodology, and, if so, on the appropriate design of any such transition. We described in the FY 2021 IPPS/LTCH proposed rule that when we adopted the cost-based MS–DRG methodology for FY 2007 IPPS payments, we provided a 3-year transition from the charge-based MS–DRG relative weight calculation to the cost-based MS–DRG relative weight calculation (71 FR 47898). We recapped that for the first year of the 3-year transition of the relative weights, the relative weights were based on a blend of 33 percent of the cost-based weights and 67 percent of the charge weights. In the second year of the transition, the relative weights were based on a blend of 33 percent of the charge weights and 67 percent of the cost-based weights. In the third year of the transition, we noted that the relative weights were based on 100 percent of the cost-based weights. We requested comments, in the FY 2021 IPPS/LTCH proposed rule, on whether we should provide a similar type of transition from a cost-based weight methodology to a market-based weight methodology.

Lastly, we noted in the FY 2021 IPPS/LTCH proposed rule that in future rulemaking, we may consider ways to further reduce the role of hospital chargemasters in Medicare IPPS payments and further reflect market-based approaches in Medicare FFS payments. In particular, we requested comments on alternatives to the current use of hospital charges in determining other inpatient hospital payments, including outlier payments and new technology add-on payments, to the extent permitted by law.

As described further in the following sections, we are finalizing that hospitals would report on their Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations (also referred to as MA organizations) payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. At this time, we are not finalizing the requirement that hospitals would report on their Medicare cost report the median payer-specific negotiated charge the hospital has negotiated with all of its third party payers by MS–DRG, as proposed. Additionally, we are finalizing the adoption of a market-based MS–DRG relative weight methodology for calculating the MS–DRG relative weights, beginning in FY 2024, as described in the proposed rule, and which we indicated we may consider finalizing in this FY 2021 final rule. The market-based MS–DRG relative weight methodology would utilize the median payer-specific negotiated charge data negotiated between hospitals and MA organizations.

We are finalizing the requirement that hospitals would report on their Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, and not finalizing the requirement with respect to all of its third-party payers, for two primary reasons. These reasons take into account commenters' feedback on the relationship between MA organization rates and Medicare FFS rates, which was also supported by our literature review, feedback on the potential challenges in comparing data across all third party payers based on the variety of ways hospitals and other third party payers negotiate charges, and concerns expressed regarding Medicare payment impacts. First, we agree that there may be potential challenges in comparing data across all third party payers based on the variety of ways hospitals and other third party payers negotiate charges. It may take additional time to adequately address these challenges. We believe based on the closer relationship between MA organization rates and Medicare FFS rates that these challenges are mitigated, and therefore the collection and use of the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers allows the incorporation of market-based pricing calculations within our Medicare payment calculations sooner. Second, we believe that based on the closer relationship between MA organization rates and Medicare FFS rates that using the MA organization data will provide a more moderate impact on the MS–DRG relative weights calculated under a market-based MS–DRG relative weight methodology.

We will make our analysis of this market-based data available for public review prior to the effective date of this policy in FY 2024. As described in the proposed rule, we remain open to adjusting this finalized policy, through future rulemaking, prior to the FY 2024 effective date. We are not finalizing, at this time, a transition period to this market-based MS–DRG relative weight methodology, but may consider this in future rulemaking prior to FY 2024. We expect that, for some period of time, as discussed in the proposed rule, we would continue to estimate and publicly provide the MS–DRG relative weights calculated using the cost-based estimation methodology for informational purposes after implementation of the new market-based methodology.

In this section, we summarize and respond to the public comments received. Commenters included individuals, consumer and patient advocacy organizations, hospitals and health systems, hospital and state hospital associations, medical associations, health benefits consultants, health information technology (IT) organizations, and academic institutions, among others. We note that some commenters raised concerns with the Hospital Price Transparency final rule requirements (84 FR 39571), which we consider out of scope as they discussed policies previously finalized under a separate notice and comment rulemaking.

Comment: A few commenters requested that if CMS proceeded to collect this market-based data and utilized it within the MS–DRG relative weight methodology that CMS should proceed with caution. Some commenters believed CMS was conflating market rates with cost and noted that utilization of various MS–DRGs are dissimilar between Medicare, Medicaid, commercially insured, and worker's compensation patients. Commenters also argued that this data was not representative of the hospital resources used when providing inpatient care. Other commenters believed chargemaster rates rarely reflect true market costs, and that there are other rate-influencing factors to consider. Other commenters believed that since CMS uses hospital charges from the MedPAR claims data and cost report data from the Healthcare Cost Report Information System (HCRIS) to establish the MS–DRG relative weights, that CMS does not rely solely on the

chargemaster and already uses market based information.

A commenter speculated that over time, the MS–DRG system could become obsolete and fail to be reflective of new technologies and the relative hospital resources needed to provide state of the art, cost-effective care. Another commenter believed rates should reflect resource intensity, and that lower reimbursement without reference to resources would result in employment cuts and ultimately a reduction in access to care, including service line and hospital closures. A few commenters stated the adoption of a national market-based payment methodology would cripple the ability for sole community hospitals and rural hospitals to continue to provide care at the current levels the communities depend on and would result in closures of hospitals. Another commenter believed that the proposal may redistribute payments across services based on the relativity of payments for different patient populations, but that it would not increase competition. A commenter believed that the proposal would only change a single factor of determining an IPPS payment, the relative weight, but nothing else.

Response: We recognize that the chargemaster is only one component of current Medicare payment methodologies, but that by moving to a market-based MS–DRG relative weight methodology in FY 2024, we will begin to reduce our reliance on the hospital chargemaster. As we noted in the CY 2020 OPPS proposed rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we will continue to examine ways to further incorporate market based strategies within Medicare FFS payments, including to further examine the current use of charges converted to cost in setting Medicare payment for hospital services as part of our larger goal of reducing reliance on the hospital chargemaster. As noted in the proposed rule (85 FR 32790), we sought public comment within the CY 2020 OPPS PPS proposed rule (84 FR 39609) on ways to improve these aspects of the current hospital payment system. As discussed in the proposed rule, we received public feedback indicating that the use of hospital charges for payments and ratesetting is viewed as the most significant barrier to hospitals' efforts to change their chargemasters (85 FR 32790).

General economic principles indicate that a firm would not operate at a loss in the long-run, otherwise it would face a shutdown.[446] We believe that payer-specific negotiated charges that hospitals negotiate with MA organizations capture the relative resources used to provide services to patients in order to maximize profits (or, in the case of not-for-profit hospitals, net income). By using market-based data, we believe that we can reduce our reliance on the hospital chargemaster and utilize this data in Medicare payment methodologies so that payments more closely reflect the true market cost and therefore the relative market value and resource utilization for inpatient items and services.

We disagree that this market-based data would not provide an appropriate basis for estimating the relative hospital resources used with respect to discharges classified within a single MS–DRG compared to discharges classified within other MS–DRGs. We believe that it is important that the MS–DRG relative weights reflect true market costs and resource utilization, as discussed in the FY 2021 IPPS/LTCH PPS proposed rule. This concept was supported by commenters that stated chargemaster (gross) rates rarely reflect true market costs. We believe that by reducing our reliance on the hospital chargemaster that we can adjust Medicare payment rates so that they further reflect other factors that may change the relative use of hospital resources, as permitted and required by section 1886(d)(4)(C)(i) of the Act. We disagree with the commenter that argued we already use market-based information within our current MS–DRG relative weight methodology, given other commenters' statements about how chargemaster (gross) rates rarely reflect true market costs.

We remain committed to engaging with commenters regarding the concerns they raised with the potential for payments to be redistributed based on different patient populations. We also intend to provide our analysis of the market-based data for public review, prior to the implementation of the new MS–DRG relative weight methodology in FY 2024.

We were persuaded by commenters' requests that we take a more measured approach when adopting a market-based MS–DRG relative weight methodology. As discussed previously, we believe there will be minimal impacts to the relative weights calculated under the new market based MS–DRG relative weight methodology (which would utilize the median payer-specific negotiated charge data negotiated between hospitals and their MA organization payers) beginning in FY 2024, given the relationship between the MA organization rates and Medicare FFS rates (as evidenced by feedback from commenters and the results of our literature review). We refer readers to the Appendix A of this rule for further description of the impact analysis.

Comment: A few commenters offered sentiments related to the directives under Executive Orders 13813 and 13890, expressing that they did not believe the collection of information proposed in the rule was mandated or reasonably related to the goals of increasing consumer choice and promoting competition as outlined in the Executive Orders. A commenter believed that the proposed rule directly contradicts with the policy goals of the Executive Orders by relying on federal ratesetting in lieu of true market-based pricing.

Response: We thank commenters for their feedback. We clarify that the goal of this final policy is to reduce our reliance on the hospital chargemaster by incorporating market-based data within Medicare FFS payments. Further, we disagree with the notion that the collection of information proposed in the rule is not reasonably related to the goals outlined in Executive Orders 13813 and 13890. We believe these policies align with our goal of reducing the Medicare program's reliance on the chargemaster and adopting payment strategies that are more reflective of the commercial insurance market, which were themes also addressed with Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors, which President Trump issued on October 3, 2019.

Comment: Several commenters supported the proposal to report market-based rate information on Medicare cost reports. These commenters noted that by requiring the reporting of these market-based summary measures that CMS would further promote greater transparency in health care pricing and more accurate market-based reimbursement within the Medicare Fee-For-Service system that would be subject to less manipulation and inflation by hospital-set chargemaster prices. Other commenters supported our data collection proposal, because they viewed it as helping fix existing Medicare payment policy issues that have increased payments calculated off of hospital reported gross charges. A commenter noted that hospital chargemasters have long been seen as an

[446] *See* Phelps, Charles E. Health economics. 3rd edition. Boston: Addison-Wesley, 2002. Pp. 271–275. *See also* Varian, H.R. (2004). Microeconomic analysis. 1992. New York, London: WW Norton & Company. Chapter 2. (General economic principles state that firms do not operate at a loss.)

arcane and outdated accounting system. This commenter stated that, ''the chargemaster system has endured over time because payers have developed methodological approaches to establish payments that do not equate to hospital charges.'' A commenter suggested CMS also require reporting of patient specific cost sharing and align cost with quality. A few commenters recommended focusing on providing consumers with the cost and quality information that they stated was needed to make informed healthcare purchasing decisions. However, a commenter noted that the disclosure of the median negotiated rate alone does not sufficiently unveil underlying pricing and revenue management objectives.

Response: We thank the commenters for their support of our proposals to report the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations and median payer-specific negotiated charges for third party payers by MS–DRG on the Medicare cost report, and the support of utilizing this data within a market-based methodology for calculating IPPS MS–DRG relative weights that is more reflective of market-based pricing. We agree with commenters' assertions that it may be time to reduce our reliance on the hospital chargemaster so Medicare FFS payments further reflect the relative market value for inpatient items and services. The purpose of this data collection requirement is to collect market-based data so that the data may be used within Medicare payment calculations. As it is true for all data collected in the Medicare cost report, this information will be publicly available on the HCRIS data set. In response to commenters concerns with the reporting of certain cost sharing information, we refer readers to the Hospital Price Transparency final rule for specific information on this type of disclosure (84 FR 65524).

Comment: Some commenters expressed concern regarding the utility of collecting median payer-specific negotiated charges by MS–DRG for payers that are MA organizations and the median payer-specific negotiated charges by MS–DRG for third party payers. Specifically, some commenters were concerned that the median payer-specific negotiated charge for MA organizations would not be useful as they only reflected the rates paid under Medicare Fee-For-Service. Other commenters expressed concern that because MA organization rates were set based on previous rates of Medicare FFS, they would set-up a system with no updates in rates to reflect changes or continued reductions. Many commenters expressed concern about the difficulty of comparing charges used under the MS–DRG systems to different systems used by commercial payers, and that crosswalking charges from one classification system would be burdensome to calculate and may introduce variation in the relative rates. Some commenters argued that this could disrupt competition in the market.

Many commenters expressed concern about the comparability of charges negotiated for Medicare Advantage, Medicare FFS and third party payers, and questioned CMS's capability to account for different negotiation tactics. Commenters suggested that Medicare Advantage patients may be healthier and have lower risk than Medicare FFS patients, while generally the Medicare population may be older and have more comorbidities compared to the beneficiary population served by commercial payers. Commenters also discussed that some commercial payers may cover certain services that are not covered by Medicare, and that there may be certain types of payment structures that are singular to the Medicare program that do not translate to commercial insurance practices. A few commenters suggested that commercial rates may be negotiated using different tactics to account for different risk arrangements, such as: Episodes of care, separately negotiated outlier payments, stop loss provisions, quality payment, capitated payments, claw-back provisions or acquisition costs that would not easily be comparable, and that CMS should describe how the median payer-specific negotiated charge calculation will account for these arrangements. Without accounting for these arrangements, a few comments suggested that utilizing this market-based data for Medicare FFS payments could shift costs to the private sector.

A commenter suggested that hospitals are required to be paid Medicare FFS rates by MA organizations with which they do not contract, so the reported charges might not reflect negotiated charges. Several commenters expressed concern that those rates were affected by matters outside of the costs of care and may reflect market dynamics and broader issues associated with negotiating a large number of healthcare services.

Response: We appreciate the additional feedback from commenters regarding differences in potential reimbursement methodologies among the different commercial payers and MA organizations, and the presence of different payment contracts between hospitals and payers, specifically among commercial payers. We thank commenters for their concerns regarding the comparability of payer-specific negotiated charges by MS–DRG for all third party payers given the myriad of negotiation tactics that may be used when third party payers negotiate with hospitals. As noted previously, we were persuaded by commenters' concerns and are finalizing only to collect and utilize the median payer-specific negotiated charge negotiated between hospitals and MA organizations.

We recognize, based on the literature review we conducted and feedback from commenters, that MA rates and Medicare FFS rates are often similar and/or are highly reliant on one another. However, MA rates to MA contracted inpatient hospitals are not required to be the same as (or based on) Medicare FFS rates; the Medicare statute only requires MA organizations to pay FFS rates to a health care provider for services furnished to an MA enrollee when the MA organization does not have a contract with the health care provider. We believe that if market based data (median payer-specific negotiated charges for MA organizations) are incorporated into the calculation of the MS–DRG relative weights, initially there may be limited impact on the relative weights given the highly reliant nature between MA organization and Medicare FFS rates, but that over time markets will adjust to this policy and further influence the Medicare FFS payments. We also appreciate the additional feedback from commenters regarding the characteristics of beneficiaries that choose an MA plan. Our review and analysis of the market-based data collected, as discussed previously, may allow us to explore those relationships further.

Comment: Several commenters expressed concern with the requirement to disclose negotiated rates and make them publicly available through the Healthcare Cost Report Information System (HCRIS) dataset, saying the negotiated rates are confidential and proprietary. A few commenters expressed concern that in health care markets with a small number of payers, these proposals would allow for the re-identification of the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations. A commenter expressed concern that the public release of MA charge data may encourage hospitals to stop participating in MA plans. A commenter suggested that information should not be reported if the hospital is in a region with a low

number of MA plans in order to avoid revealing the actual charges for individual MA plans.

Response: We disagree with commenters, and note that the negotiated amount is already disclosed to patients when they receive the explanation of benefits for services received. We also disagree with commenters' assertion that public release of MA charge data may encourage hospitals to stop participating in MA plans. As noted in the proposed rule, we will be requiring hospitals to report the median, which is a summary measure. We are not requiring that the hospitals report the negotiated charge and corresponding payer for which they have negotiated the charge information. We remind readers that we are requiring the collection of this market-based measure on the Medicare cost report for purposes of utilizing the data within Medicare payments. This information will be publicly available, along with all other data reported on the Medicare cost report, on the HCRIS dataset, for the purposes of calculating Medicare payments and will continue to provide full transparency to the public on how these payments, and others, are calculated.

Comment: Several commenters requested refinements or clarifications in information that would be reported by hospitals on the Medicare cost report, and requested more detail on how hospitals should account for certain factors and payments when calculating the median payer-specific negotiated charge. A few commenters requested that the full distribution of charges be included, not just the median. A commenter requested clarification on whether the median payer-specific negotiated charges would include or exclude items such as disproportionate share hospital payments, uncompensated care payments, graduate medical education payments, pass through payments, outlier payments, transfer adjustments, and quality program payments. A commenter requested clarification on whether hospitals should report the average negotiated charge based on historical claims data for payers that have negotiated a per diem or a percentage of charge arrangement and also do the same for those payers that have negotiated a base MS–DRG rate plus percentage of charge for devices that are in addition to the base rate. Commenters made several requests: That averages be reported instead of medians due to the difficulty of calculating medians; a discount rate be reported in addition to median charges; CMS limit data collection to a representative sample of hospitals as opposed to requiring all hospitals to report; CMS provide clearer guidance for reporting the charges associated with MS–DRGs and how discounts might be applied in the calculation; guidance on the inclusion of items such as uncompensated care and quality program adjustments in performing the calculation; and that outliers be removed for purposes of calculating charges.

Response: We believe that hospitals have the capacity, based on the instructions provided within this final rule, and the forthcoming revision of the Information Collection Request currently approved under OMB control number 0938–0050, expiration date March 31, 2022, to report this data on the Medicare cost report for cost reporting periods ending on or after January 1, 2021. We may provide additional guidance as appropriate or as determined necessary. Absent additional guidance, we believe that hospitals have the capability to report this market-based data for cost reporting periods ending on or after January 1, 2021.

While commenters suggested CMS clarify the reporting instructions to hospitals and also describe how we planned to take into account several factors when standardizing the market-based data once it was collected, commenters did not provide examples or recommendations for how to specifically adjust or account for these factors. We note that, as described previously, the market-based MS–DRG relative weight methodology, as finalized in this final rule, would standardize the market based data collected under section IV.P.2.d. of this final rule for area wage levels and cost-of-living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the cost-based MS–DRG methodology (Step One of the market based MS–DRG relative weight methodology). We believe this action would adjust for geographic factors referenced by commenters. As noted in the proposed rule, under Step Two of the market based MS–DRG methodology, we would standardize the median payer-specific negotiated charge data by the hospital's Medicare transfer-adjusted case count for that MS–DRG, with transfer adjusted case counts calculated the same way as under the current cost-based MS–DRG relative weight methodology (84 FR 42621). We note that quality payment adjustments are not accounted for within the existing MS–DRG relative weight process. We remain open to adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date.

Comment: A commenter supported the alternative of requiring the reporting of a median negotiated reimbursement amount across all MA organizations and across all third-party payers by MS–DRG. Several other commenters supported our alternative proposal of limiting the data collection requirement to only the median payer-specific negotiated charges by MS–DRG for payers that are MA organizations, and noted that they opposed reporting any market-based data but favored the reporting of Medicare Advantage data only over reporting charges for other payer types.

Several commenters opposed the alternative of reporting of a median negotiated reimbursement amount across all MA organizations and across all third-party payers by MS–DRG. These commenters primarily expressed concern over the technical challenge and burden of calculating this data suggesting that matching negotiated rates to an MS–DRG is not straightforward and would require significant time and labor by hospitals because reimbursement methodologies vary significantly by payer. A commenter suggested that this would require more work as the calculation could not be derived from the files created under the requirements of the Hospital Price Transparency rule.

Response: For the reasons discussed previously, we are finalizing the collection of the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations for cost reporting periods ending on or after January 1, 2021. We are not finalizing the collection of the median negotiated reimbursement amount measure or another alternative measure, as discussed in the proposed rule, because we were persuaded by commenters that calculating and reporting this alternative would require a high level of effort since it would not be derived from files created under the requirements of the Hospital Price Transparency rule.

Comment: Some commenters expressed concern that requiring the reporting of median payer-specific negotiated charges raises numerous Constitutional and antitrust issues. Commenters argued that forced disclosure of negotiated rates unconstitutionally compels speech in violation of the First Amendment. Commenters argued that the reporting of payer-specific negotiated rates does not advance the agency's goals of adopting a more market-based pricing strategy and there are ways for CMS to achieve

this goal without requiring compelled speech.

Commenters also asserted reporting of payer-specific negotiated charges violates the Takings Clause by forcing the disclosure of trade secret information (that is, confidential negotiated rates between hospitals and issuers). Additionally, commenters argued that requiring providers to report payer-specific negotiated rates crosses into infringement of antitrust laws and places hospitals in an untenable position of having to choose between violating their contractual obligations for confidentiality and violating the new rule. Commenters argued that compliance with this data collection requirement may put hospitals in legal jeopardy under contractual confidentiality provisions or under state trade secrets laws.

Response: We do not believe that the payer-specific negotiated charges hospitals would be required to disclose would constitute trade secrets. To the contrary, this information is already generally disclosed to the public in a variety of ways, for example, through State databases and patient explanation of benefits (84 FR 65544).

We also question whether our collection of data via the cost report raises a First Amendment issue. Federal agencies routinely require regulated entities to disclose data to the government. To the extent that our rule is deemed to implicate First Amendment concerns, it satisfies applicable requirements. Under the approach articulated in *Zauderer,*[447] courts uphold the required disclosures of factual information in the realm of commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome such that it would chill protected speech.[448] These disclosures also satisfy the test articulated in *Central Hudson,*[449] under which agencies can compel speech where the regulation advances a substantial government interest and the regulation is no more extensive than necessary to serve that interest. The policies finalized in this final rule advance the substantial government interest in setting MS–DRG relative weights based on hospital resource use, and the requirement to disclose a summary measure on a cost report does not burden the hospitals' speech in any way, and we do not understand commenters to be arguing otherwise. To the extent that commenters assert that the rule creates a burden in terms of compliance costs, we believe that such costs are not a burden on speech specifically and therefore do not implicate the First Amendment.

As detailed in the proposed rule, we are specifically requiring that hospitals report the median, which is a summary measure. We proposed to collect the median of the hospital payer-specific negotiated charges by MS–DRG, because the median is a common measure of central tendency that is less influenced by outlier values; however, we note that in the event a hospital has listed an even number of payer-specific negotiated charges by discharges for that specific MS–DRG, the hospital, in its calculation of the median, would use the average of the two remaining payer-specific negotiated charges in order to calculate the median; this will further de-identify the payer-specific negotiated charge data required under this policy.

Comment: Commenters urged CMS not to finalize the market-based payment proposal, asserting that privately negotiated rates will not further CMS's goal of paying market rates, while others expressed concern that CMS had not articulated a sufficient policy basis for using payer-specific negotiated charges as a substitute for hospital data to calculate the IPPS relative weights. Commenters argued that CMS did not provide sufficient analysis or rationale to show that payer-specific negotiated charges measure a hospital's relative resource use for a particular MS–DRG, as required by statute.

A few commenters noted that negotiations are based on multiple factors, of which cost is one factor, and that the current cost-based relative weight methodology adequately captures hospital relative resource use. A commenter argued that after reviewing the proposal with the statutory language contained in sections 1815(a) and 1833(e), they were concerned that CMS may be citing baseless authorities, and that CMS should also comply with section 1861(v)(1)(A) of the Act. The commenter stated that all other complexity added after this provision, whether it is the determination of cost-computing methods or the distillation of cost into specific metrics or units, does not negate the foundational requirement that hospitals must ''incur'' something in order to report it. The commenter urged CMS to explain the discrepancy between the proposed rule and the plain language of statutory authorities before finalizing. Commenters further argued that CMS did not adequately explain why market prices, rather than costs, are a better measure of hospital resources and, therefore, the proposed rule constitutes an arbitrary and capricious rulemaking, violating the Administrative Procedure Act.

Response: We disagree with commenters that stated we did not articulate a sufficient policy basis for our data collection policy. As discussed in the proposed rule, sections 1815(a) and 1833(e) of the Act provide us with the authority to collect data for purposes of determining the amount of payments due to the provider under the Medicare program. We proposed to collect this negotiated charge data so that it may be used in determining relative weights for purposes of payment under the IPPS.

CMS also has authority to assign and update MS–DRG weighting factors to reflect relative resource use. As previously discussed, section 1886(d)(4)(A) of the Act states that the Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. Section 1886(d)(4)(B) of the Act states that for each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. Section 1886(d)(4)(C)(i) of the Act states that the Secretary shall adjust the weighting factors at least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources. As noted by commenters, relative resources are accounted for when hospitals establish the cost of services, and costs of services are considered when negotiating with payers. Because of this, we believe that relative resources are one of the factors considered when negotiating amounts between hospitals and payers, and therefore the payer-specific negotiated charge would reflect relative resources used. We believe that relative resources are accounted for when hospitals and payers negotiate payments and would be captured within payer-specific negotiated charge data reported on the Medicare cost report by MS–DRG, as previously described.

Commenters noted that hospitals may negotiate based on the market share, cost of services, risk of certain services,

[447] *Zauderer* v. *Office of Disciplinary Counsel,* 471 U.S. 626 (1985).

[448] See *Zauderer,* 471 U.S. at 651; *Milavetz* v.*United States,* 559 U.S. 229, 250, 252–53 (2010); *NIFLA,* 138 S. Ct. at 2376 (''[W]e do not question the legality of . . . purely factual and uncontroversial disclosures about commercial products.'').

[449] *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557 (1980).

patient population, and other factors, but did not articulate why the resources necessary to perform these services based on these negotiation tactics would not be considered in a hospital's starting point negotiations with payers. If costs are considered when hospitals are negotiating payments, and commenters stated the current system of establishing MS–DRG relative weights, which is a cost-based methodology, accounts for relative resources used, then we do not agree that negotiated charges would not encompass relative resources used. The commenters seem to suggest that a hospital would consider utilization when negotiating its contracts, but not the resources necessary to provide those items and services for that level of patient utilization anticipated. As discussed previously, general economic principles indicate that a firm would not operate at a loss in the long-run or would face a shutdown.[450] We believe the rates that hospitals negotiate with MA organizations capture the relative resource use to provide services to patients in order to maximize profits (or, in the case of not-for-profit hospitals, net income), subject to market constraints and conditions (supply and demand, community benefit requirements, etc.). Therefore, we believe that payer-specific negotiated charges provide greater insight into the resource use of a hospital.

We also believe that these data can be used in determining the relative resource use for an MS–DRG. The market-based MS–DRG relative weight methodology, which we are finalizing with a FY 2024 effective date, would create the relative weight by calculating the ratio of the single weighted average standardized median MA organization payer specific negotiated charge for *that* MS–DRG across hospitals (Step 2) to the single national weighted average standardized median MA organization payer-specific negotiated charge across *all* MS–DRGs (Step 3). By virtue of calculating this ratio establishing the relativity, the weights would reflect the resources used with respect to a discharge classified within that group.

To the commenter's specific point that rather than the authority we cite, CMS should focus on section 1861(v)(1)(A) of the Act, we note that we did include a reference to the requirement that providers follow reasonable cost principles under Section 1861(v)(1)(A) of the Act when completing Medicare cost reports. We further note that Section 1861(v)(1)(A) of the Act requires reporting of data elements beyond just cost, including non-cost items and items used to determine the cost of services.

Comment: Many commenters recommended that CMS not proceed with this proposal because the validity of the Hospital Price Transparency final rule is pending appeal before the U.S. Court of Appeals for the D.C. Circuit, in which several hospital associations and individual hospitals are seeking to invalidate that rule. *See* Am. Hosp. Ass'n v. Azar, 2020 WL 3429774 (D.D.C. June 23, 2020), appeal pending, No. 20–5193 (D.C. Cir. docketed June 30, 2020). Furthermore, commenters stated that because they believed CMS did not have the authority to collect this market-based data, that CMS therefore could not proceed with utilizing this data under the potential market-based MS–DRG relative weight methodology, as described in the proposed rule.

Commenters recommended that CMS should not proceed with this proposal, or at a minimum it should wait until the legality of the Hospital Price Transparency final rule is settled by the Courts.

Response: CMS did not rely on the statutory authority under 42 U.S.C. 300gg–18(e) for purposes of the proposed collection of the median negotiated charge information on the Medicare cost report, nor for purposes of the potential change in the relative weighting methodology. We refer the commenters to our prior responses for a discussion of the relevant statutory authority for purposes of this rulemaking as well as our prior discussions responding to various constitutional concerns.

Comment: Many commenters expressed concern that there were several potential unintended consequences of collecting market-based data and utilizing that data to establish MS–DRG relative weights. Specifically, several commenters noted that there had been recent state action addressing health care price transparency, the results of which have not yet been assessed. Commenters noted that neither CMS nor independent researchers have produced analyses that suggests that negotiated charge data are reliable, reasonably consistent across hospitals, or representative of the FFS population. Commenters argued that given the lack of a publicly available dataset containing negotiated charge data, they cannot determine any potential unintended consequences of these data.

Several commenters cautioned CMS to consider the downstream effects of potentially adopting a market-based MS–DRG relative weight methodology and requested that CMS adopt a more moderate approach, should CMS adopt this market-based methodology. Specifically, commenters were concerned about the incorporation of quality-based payments and recommended CMS engage stakeholders to determine how this policy aligns with the adoption of value-based contracting arrangements. Commenters noted that establishing a policy that ignores value-based arrangements stymies the progression to value-based arrangements. Another commenter argued that many value-based bundled payment models require reconciliation well after the time of the patient encounter. Other commenters noted that certain payment arrangements may result in the final negotiated amount differing from the ''base'' negotiated rate, such as in capitated arrangements. If CMS adopted a market-based MS–DRG relative weight methodology that utilized payer-specific negotiated charge data, commenters requested that CMS publish this information so commenters could replicate and review the calculation of the MS–DRG relative weights under this market-based methodology, as commenters argued is CMS's current practice under the cost-based MS–DRG relative weight methodology.

Some commenters recommended that CMS task a multi-stakeholder group of subject matter experts to gather the necessary data, conduct a thorough and transparent analysis of the reliability of the data, and evaluate a range of methodologies with the sole purpose of identifying mechanisms to make payments more value-based and reflective of the actual true relative hospital resources used to deliver care. Other commenters recommended that CMS, limit the scope of this data reporting requirement to a small representative sample of hospitals and use that data to evaluate the impact it would have more broadly, consider phasing-in this methodology over time, and establish guardrails that would limit the year-to-year change on MS–DRG relative weights to a certain percentage. A few commenters recommended that CMS delay implementation until the agency has adequately explained the basis for concluding that payer-specific negotiated charges by MS–DRG reflect resources used and stakeholders have had another opportunity to comment on the proposal. A few commenters

[450] *See* Phelps, Charles E. Health economics. 3rd edition. Boston: Addison-Wesley, 2002. Pp. 271–275. *See also* Varian, H.R. (2004). Microeconomic analysis. 1992. New York, London: WW Norton & Company. Chapter 2. (General economic principles state that firms do not operate at a loss.)

requested CMS first evaluate and report to House and Senate Committees of Jurisdiction on the extent to which charge data that would be reported under the Hospital Price Transparency final rule would reflect market-based pricing dynamics, and the resultant impact that would have on the IPPS MS–DRG relative weight. Another commenter believed that CMS's proposal could be a diversion from mission-critical efforts and would therefore be at odds with other CMS policies intended to reduce the paperwork burden and enhance policy flexibilities for health providers, such as the Patients over Paperwork Initiative and the Quality Payment Program.

Response: We agree with commenters that we should provide an additional opportunity for the public to review the market-based data collected under section IV.P.2.c. of the final rule. We intend to provide an opportunity for the public to review our analysis of the median payer-specific negotiated charge data received, which we intend to do prior to the utilization of the MA organization median payer-specific negotiated charge data in the market-based MS–DRG relative weight methodology beginning in FY 2024. We believe this allows for additional discussions, public review, and conversation about utilizing this market-based data in the MS–DRG relative weight methodology. We also were persuaded by commenters' concerns that collecting all third party payer payer-specific negotiated charge data would not provide for a direct data comparison between hospitals, because of the different negotiation tactics used and beneficiary populations served by the commercial insurance market. We believe that by instead collecting and utilizing MA organization negotiated charge data, we are finalizing a more moderate approach.

Comment: Several commenters disagreed with how the term ''charges'' was defined and expressed concern that CMS's inconsistent use of the term may cause confusion. Commenters recommended that CMS provide a clearer definition to the proposed requirements. A commenter requested that CMS use more precision in their language to clarify that ''charges'' only reflect amounts in the hospital chargemaster. The commenter stated that given all the variations in patients' unique situations and other variables in contract terms, it would be nearly impossible for providers to comply consistently. Furthermore, another commenter emphasized that it is counterintuitive for CMS to disregard the Provider Reimbursement Manual (PRM) when it comes to the definition of ''charges'' but rely on it heavily when it comes to questions of Medicare bad debt. The commenter referenced a section of the PRM that states ''charges should be uniformly applied to all patients'' and asserted that by CMS's definition a payer-specific negotiated charge cannot be considered a standard charge, simply because the same charge is not applied to all patients. Another commenter suggested limiting the word ''charges'' to ''gross charges'' listed for items and services on the hospital's chargemaster. The commenter also suggested that the word ''rate'' refer to the negotiated payment amount or price of a particular service. Additionally, another comment recommended that CMS replace the term charges with rates altogether. Lastly, a commenter advised CMS to carefully consider the definition of ''cost'' because the term is misleading.

Response: We appreciate the commenters' request for clarity and precision in CMS's definitions with respect to this proposal. For the purposes of this rule, we proposed, and are finalizing, to define ''payer-specific negotiated charge'' as the charge that a hospital has negotiated with a third-party payer for an item or service. As discussed in the proposed rule, we proposed to use this definition because it would capture the charges that are negotiated between hospitals and MA organizations, and hospitals and all its third party payers, including MA organizations, and can provide the data needed to evaluate the use of market-based information for payment purposes within the MS–DRG relative weight calculation. This definition of payer-specific negotiated charge is the same definition of ''payer-specific negotiated charge'' that we finalized for the purposes of hospitals making their standard charges available to the public under the Hospital Price Transparency final rule. We note that the definition of third party payer, for the purposes of reporting median payer-specific negotiated charges set forth in this rule, includes MA organizations that have contracted with CMS. As we have discussed, because hospitals are already required to publicly report payer-specific negotiated charges under the final policy set forth in the Hospital Price Transparency final rule, using the same definition of payer-specific negotiated charges required for posting under the Hospital Price Transparency final rule to calculate the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations, as required under this final rule, reduces burden on hospitals.

Additionally, we responded to many of these same comments in the Hospital Price Transparency final rule; we refer readers to the Hospital Price Transparency final rule (84 FR 65541) for the discussion regarding ''standard charges''.

Comment: A commenter opposed aspects of CMS's definition of ''items and services.'' In particular, the commenter disagreed that MS–DRG items and services are established as standard charges in inpatient settings. The commenter acknowledged services provided for a particular MS–DRG are quite similar across patients; however, the commenter stated that hospitals generally do not establish a standard charge for an inpatient admission. Instead, there are often standard negotiated rates for inpatient admission equal to the product of rate and the negotiated relative weight of the MS–DRG.

Response: We believe that since hospitals assign the underlying ICD–10–CM principal diagnosis, and any other secondary diagnosis codes and ICD–10–PCS procedure codes, which determine how patients are assigned to an MS–DRG, that hospitals are able to associate those items and services to MS–DRGs for each discharge. Additionally, hospitals that are not as familiar with MS–DRGs have access to the most current publically available version of the CMS Grouper used to group ICD–10 codes to MS–DRGs, and are able to use this software to uniformly group inpatient items and services to MS–DRGs, either initially by proactively using the same Grouper version used by CMS, or retrospectively after an inpatient hospital stay, but prior to submitting this information on the hospital cost report. This definition of ''items and services'' is the same definition of ''items and services'' that we finalized for purposes of our requirements for hospitals to make their standard charges available to the public under the Hospital Price Transparency final rule, except that we have omitted the reference to outpatient department visits, because we would not require hospitals to calculate the median payer-specific negotiated charges for items and services provided in the hospital outpatient setting under this requirement. As we have discussed, because hospitals are already required to publicly report payer-specific negotiated charges under the final policy set forth in the Hospital Price Transparency final rule, using the same definition of ''items and services,'' as required for posting under the Hospital

Price Transparency final rule, to calculate the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations, reduces burden on hospitals.

Comment: A commenter disagreed with CMS's definition of ''third party payer'' and suggested CMS consider explicitly excluding payers that would not logically fit within a hospital's MS–DRG relative weight calculation, such as stand-alone dental plans.

Response: We thank this commenter for their input; however, we believe that using this definition of ''third party payer,'' which we note includes MA organizations and is also the definition of third party payer finalized for purposes of the Hospital Price Transparency final rule, reduces burden on providers as discussed previously. Additionally, because the Medicare FFS program provides for limited coverage of dental procedures, there may be limited instances where dental items and services would be grouped to an MS–DRG.

Comment: A few commenters expressed concern that long term care hospitals (LTCHs) will be directly and significantly affected by the change in methodology for calculating MS–DRG relative rates. A commenter expressed concern that the proposed changes to IPPS payment rate setting will further destabilize the LTCH PPS for many Medicare beneficiaries. This commenter noted that the LTCH PPS utilizes the IPPS rates to determine the site neutral payment rate used for LTCH admissions that do meet the LTCH patient criteria. Second, these commenters noted that IPPS payment rates are used in the LTCH PPS payment rate for short-stay outlier cases where the payment rate is a blend of the IPPS per diem amount and 120% of the LTC–DRG per diem amount. Another commenter expressed concern that because LTCHs contract with Medicare Advantage differently from other hospitals, their data would not be useful in determining charges. Commenters recommended that CMS further clarify how the proposed rule will impact post-acute care hospitals, including LTCHs.

A commenter urged CMS to revise the proposed regulation so that it clearly limits these new reporting requirements to short term acute care hospitals paid under the IPPS. Another commenter strongly opposed any attempt to expand data collection to LTCHs. A commenter requested sole community hospitals be exempt from this regulation. While other commenters requested that CMS clarify whether non subsection (d) hospitals would be exempted from this data collection proposal.

Response: We did not propose any changes to the LTCH PPS nor the MS–LTC–DRG methodology, only to the IPPS and MS–DRG relative weight methodology. As discussed in this final rule, we were persuaded by commenters' request that we continue to publish the MS–DRG relative weights under the cost-based MS–DRG methodology. Therefore, we expect to continue to publish the MS–DRG relative weights under both the cost-based MS–DRG methodology and the market-based MS–DRG methodology, for a period of time. This will enhance our review of the market-based data collected under IV.P.2.c. of this final rule, and will allow us to monitor for any unintended consequences, as also requested by commenters.

We are finalizing, as proposed, that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information. We note that hospitals that are not categorized under the above sections of the Act, and hospitals that do not negotiate payments for services would be exempted from this data collection requirement. We refer readers to the proposed rule (85 FR 32795) for a full discussion of this policy. We further note that we are open to adjusting any finalized policy through future rulemaking. We therefore believe that there would be additional opportunities for the public to provide feedback on our finalized policies.

Comment: Many commenters expressed concern with the timing of the implementation and stated that CMS has underestimated the time, resources, and cost required for hospitals to meet the negotiated payment data requirements by January 1, 2021. Commenters argued that due to the burden of the current COVID–19 public health emergency, CMS should delay implementation. Commenters argued that the current public health focus on COVID–19 is straining the resources of the nation's health care system. Commenters described these data collection requirements as enormous and stated that they are too administratively burdensome to implement until after the health system returns to normal, or at minimum, a commenter requested that CMS delay implementation for at least a year to give hospitals additional months to adapt to the impact of COVID–19 on healthcare utilization and payment. Additionally, a few commenters cautioned CMS from finalizing requirements for Calendar Year 2021, in order to learn from the finalized price transparency requirements already in place.

Response: We appreciate commenters' concerns about the strain on the nation's health care system due to the COVID–19 public health emergency. However, as discussed, the payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency final rule (84 FR 65524), beginning in January 1, 2021, that can be crosswalked to an MS–DRG. Hospitals would use the payer-specific negotiated charge data that they would be required to make public, as a result of the Hospital Price Transparency final rule, to then calculate the median payer-specific negotiated charges (as described further in section IV.P.2.c. of this final rule) to report on the Medicare cost report. We believe that because hospitals are already required to publicly report payer-specific negotiated charges, in accordance with the Hospital Price Transparency final rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals, because hospitals will use the payer-specific negotiated charges calculated for purposes of meeting the Hospital Price Transparency final rule requirements to then calculate the median payer-specific negotiated charge by MS–DRG for MA organizations, as required under section IV.P.2.c. of this final rule.

Additionally, the majority of Medicare certified hospitals have cost reporting periods that end between July and September of each year. Hospitals also have a 5-month period after their cost reporting periods end to submit the Medicare cost report. This means that the majority of hospitals will not submit their Medicare cost report until, at the earliest, November 2021. We will also conduct further analysis based on the market-based data received and provide an opportunity for public comment on that analysis, which may include consideration of any unknown impacts of the COVID–19 PHE on this data.

Comment: Some commenters expressed concern that CMS grossly underestimated the amount of time and burden it will take hospitals to collect, organize, properly format, calculate, update and report the median payer-specific negotiated charges by MS–DRG. Commenters argued that hospitals cannot complete the task of

implementing the reporting requirements themselves, nor have they been able to find vendors capable of accomplishing the task. Commenters noted that a health system operating in numerous states will have multiple contracts for each individual hospital, within each state, and with each payer. Commenters argued that this could result in the system needing to arrange the payer-specific negotiated charges for hundreds of discharges for a given MS–DRG across hundreds of different payer contracts in order to determine the median. Additionally, commenters argued that some third-party payers do not pay based on MS–DRGs and as a result, hospitals will need to calculate an MS–DRG based on the same or similar package of services. Commenters noted that this process becomes even more complicated if commercial plans do not pay the hospital based on FFS rates.

A few commenters provided a range of estimates for complying with the requirements of this final rule. A commenter estimated that initial compliance with the Hospital Price Transparency final rule would require a minimum of 120 hours of work, or a cost of approximately $10,000 for hospitals that have the internal technical expertise. This commenter further stated that hospitals without technical expertise would require a consultant, at the cost of $20,000 or more. This commenter argued that compliance with the policies CMS proposed would require significant effort beyond those initial requirements. Another commenter estimated it would cost around $50,000 and require a team of professionals from multiple departments to fulfill the reporting requirements. Another commenter stated the reporting requirements would entail a substantial investment of hospitals' time and resources and estimated a minimum of more than 6,000 hours per year of additional work to engage in this coding at a cost of at least $210,000. Another commenter recommended that CMS should work closely with hospitals and with the relevant financial software vendors to, at least, understand the enormity of these functions and develop a more reasonable determination of the time and cost required for a provider to comply.

A few commenters suggested that health plans, including MA plans, should instead report this data for utilization within the MS–DRG relative weight calculation and be responsible for providing consumers with pricing information. Finally, a commenter incorrectly stated that the proposal requires hospitals to post rates for outpatient surgical services, arguing that there would be a further need to post independent outpatient codes separately for items contracted individually on a FFS basis within the same grouped contracts.

Response: We note that hospitals are already required to publicly report the payer-specific negotiated charge information that they will use to calculate median payer-specific negotiated charges by MS–DRG for payers that are MA organizations, based on the requirements finalized in the Hospital Price Transparency final rule (we refer readers to burden estimates finalized in the Hospital Price Transparency final rule). We therefore believe that the additional calculation and reporting of requirements in this final rule will be less burdensome for hospitals since hospitals will already have this initial data compiled. To address the commenter's specific concerns that the rule further requires hospitals to post outpatient negotiated rates, we remind readers that our proposal, as described in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32794) and finalized in this final rule, requires hospitals to calculate and report the median of their payer-specific negotiated charges for items and services provided only in the hospital inpatient setting.

We appreciate that different hospitals may face different constraints when estimating their burden and resources required. We also acknowledge that some hospitals may require more time and resources than others to gather the relevant data, prepare for its electronic reporting, and update that information.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32887), we estimated a total annual burden to hospitals of 15 hours per hospital: 5 hours for recordkeeping, including hours for bookkeeping, accounting and auditing clerks; and 10 hours for reporting, including accounting and audit professionals' activities. We estimated an initial annual burden of 47,835 annual burden hours for 3,189 hospitals, at cost of $971.10 per hospital, or $3,096,838 across all hospitals. After consideration of the comments received, we agree that the burden estimate should be revised to reflect an increased number of hours. A few commenters provided estimates based on both their unique experiences, as well as experiences from a variety of health financial management experts and members. While commenters did not provide a range of estimated hours, the commenters that did provide dollar estimates noted the estimates fell within a range of a minimum of $20,000 per hospital to $210,000 per hospital.

We believe the estimates that commenters provided are not reasonable given the fact that hospitals are already required to publicly report the payer-specific negotiated charge information, which they will use to calculate these medians, in accordance with the Hospital Price Transparency final rule at the time that this data collection requirement goes into effect. We continue to believe that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals since hospitals are already required to have this information compiled and the burden associated with that compilation is already assumed.

We note that commenters did not provide a breakdown of the tasks and hours associated with the estimates that they provided. However, we are increasing the burden estimate after consideration of comments stating that additional effort would be necessary to crosswalk discharges to an MS–DRG, specifically if a hospital is not familiar with the MS–DRG classification system, for use in calculating the median payer-specific negotiated charges. As such, we have increased the initial estimate of 10 hours associated with reporting the median payer-specific negotiated charge to 15 hours, in order to account for this additional effort that commenters described.

Therefore, given the policies that we are finalizing in this final rule, we believe an estimate of 20 hours per hospital represents a broad industry view that takes into account the range of hospital readiness and ability to comply with these requirements. We are maintaining our estimate for the hours associated with recordkeeping at 5 and are increasing the estimate of hours associated with reporting from 10 to 15, which equals 20 hours of annual burden per hospital and 63,780 hours of estimated annual burden across all 3,189 hospitals. This equals a cost of $1,353.40 per hospital, or $4,315,993 across all hospitals.

Comment: A few commenters noted that because hospitals will be required to publicly report payer-specific negotiated charges, in accordance with the Hospital Price Transparency final rule, the additional calculation and reporting of the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations will be less burdensome for hospitals.

Response: We agree that the additional calculation and reporting of the median payer-specific negotiated charge by MS–DRG for payers that are

MA organizations will be less burdensome for hospitals.

Comment: A commenter stated that CMS may penalize hospitals that fail to provide median negotiated rates on Medicare cost reports beginning with cost reporting periods ending on or after January 1, 2021 and that those hospitals that do not report would not receive any Medicare reimbursement. The commenter stated that this punitive action is exceptionally harsh and should be re-considered.

Response: Sections 1815(a) and 1833(e) of the Act state that no Medicare payments will be made to a provider unless it has furnished information requested by the Secretary to determine payment amounts due under the Medicare program. Sections 1815(a) and 1833(e) of the Act pertain to CMS's authority to collect information on the Medicare cost report. If a Medicare provider does not furnish payment information on the cost report, then potentially no Medicare payments will be provided.

Comment: A few commenters questioned how the provisions in this regulation will impact new technology and hospital ambulatory settings within provider-based arrangements. A commenter requested if the MS–DRG weights will be updated each year and, if not, how new technology will be addressed. Another commenter noted that the regulation does not account for the posting of charges and development of median rates for hospitals with ambulatory settings within provider-based arrangements.

Response: The methodology we discussed in the FY 2021 IPPS/LTCH PPS proposed rule concerned the use of market-based data in the MS–DRG relative weight calculation, and did not address changes to new technology payments through the new technology add-on payment program, nor changes to the ambulatory payment policies. As discussed, we proposed and are finalizing the definition of the ''payer-specific negotiated charge'' as the charge that a hospital has negotiated with a third-party payer for an item or service, with an ''item and service'' being defined as all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission for which the hospital has established a standard charge. We further note that an MS–DRG, as established by CMS under the MS–DRG classification system, is a type of service package consisting of items and services based on patient diagnosis and other characteristics.

New technology add-on payment methodologies are not addressed in this policy and hospital ambulatory settings within provider-based arrangements are not included within the definition of ''items and services.''

Comment: Several commenters had suggestions of alternative approaches that they believed would reduce CMS's reliance on the hospital chargemaster. Other commenters believed that the existing cost-based relative weight methodology already reflected some market dynamics and suggested reforming the hospital cost-reporting guidance and practices to better reflect true relative hospital resources used to deliver care. Similarly, several commenters referenced an alternative model, the Direct Cost Model, which suggested that data should be derived from hospital cost accounting systems to submit an allowable cost per discharge or outpatient service. A few commenters suggested CMS should develop a multi-payer voluntary demonstration that would allow providers to work with CMS to explore ways to rebase and reset relative costs within their chargemasters based on market data. Another commenter believed MS–DRG payments should be set by patient severity and acuity rather than comparisons of various patient acuities across multiple payers.

Response: We thank commenters for their input. We are open to adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date. We welcome continued dialogue with stakeholders.

Comment: Several commenters requested that CMS continue to estimate and publicly provide the MS–DRG relative weights as calculated using the current cost-based estimation methodology along with the relative weights using the market-based estimation methodology, if CMS did finalize the market based data collection proposal and adopt a market-based MS–DRG relative weight methodology. A few commenters stated that large payers rely on CMS's MS–DRG relative weights and assignments for their pricing arrangements.

Response: As discussed previously, we were persuaded by commenters' concerns and recognize that other payers may use the CMS MS–DRG relative weights published as part of the IPPS/LTCH PPS rulemaking. We expect, for some period of time following implementation of the market-based MS–DRG relative weight methodology, as discussed in the proposed rule, to continue to estimate and publicly provide the MS–DRG relative weights calculated using the cost-based estimation methodology.

Comment: A few commenters provided a critique of Steps One through Five of the potential market-based MS–DRG relative weight methodology, which was outlined in the proposed rule. These commenters requested that CMS amend the potential market-based MS–DRG relative weight methodology, to adjust for disproportionate share hospital payments, uncompensated care payments, graduate medical education payments, pass through payments, outliers payments, transfer adjustments, quality program adjustments or other value-based purchasing arrangements, and standardize the data based on geographic region or different resource consumption such as complication or comorbidity or major complication or comorbidity, the patient population served, local market conditions, the impact of prior authorization, and other utilization management activities on the data. Additionally, other commenters suggested that it was too early for CMS to request feedback on the potential market based MS–DRG relative weights methodology since the payer-specific negotiated charge data described to be utilized within the methodology had not yet been reported or analyzed.

Response: While commenters suggested CMS take into account several factors when standardizing the data for use in the market-based MS–DRG relative weight methodology, commenters did not provide examples or recommendations for how to specifically adjust or account for these factors within the methodology. We note that, as described previously, the market-based MS–DRG relative weight methodology, as described in the proposed rule and finalized in this final rule, would adjust for geographic factors by standardizing the market-based data for area wage levels and cost-of-living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the cost-based MS–DRG methodology (Step One of the market based MS–DRG relative weight methodology). As also described in the proposed rule, under Step Two of the market based MS–DRG methodology, we would standardize the median payer-specific negotiated charge data by the hospital's Medicare transfer-adjusted case count for that MS–DRG, with transfer adjusted case counts calculated exactly the same way as under the current MS–DRG relative weight methodology (84 FR 42621). We note that quality payment adjustments are not accounted for within the existing MS–DRG relative weight process. We

remain open to adjusting our finalized policy, through future rulemaking, prior to the FY 2024 effective date.

Comment: Several commenters requested that CMS implement a transition period to monitor for unintended consequences of the new market based MS–DRG relative weight methodology. Other commenters urged CMS to provide ample transition time and clarity on the impact of changes by region and institution, while making efforts to minimize disruptions to the reimbursement system and provide certainty to hospitals and health care providers.

Response: At this time we believe it is appropriate to finalize this market-based MS–DRG relative weight methodology with an effective date of FY 2024, but we will continue to consider these comments recommending a transition period for future rulemaking. We are finalizing a FY 2024 effective data in this rulemaking because an effective date of FY 2024 is the earliest the market-based data would be available for use and we want to provide as much advanced notice to hospitals as possible.

Comment: We received comments on other issues, such as, a few commenters believed CMS did not provide enough evidence to suggest that system-wide cost reduction solely through reimbursement cuts for services delivered to beneficiaries was a driving force behind health care inflation, and suggested that CMS propose policies targeted at solving that particular problem directly. A few commenters expressed concern with the exclusion of costs associated with the overhead, handling, and other operating expenses associated with high-cost implantable devices. A commenter noted that CMS's MS–DRG relative weight calculations for procedures associated with high-cost medical devices may be underweighted and result in payments less than hospitals' costs to perform these procedures. Another commenter suggested that CMS issue new instructions for how hospitals should consistently report charges associated with high-cost implantable devices, including designating a new cost center for the purchase of high-cost implantable medical devices that includes the reporting of the acquisition cost of the medical device and the overhead expenses associated with acquisition, handling, and operating of the device. A commenter expressed concern that the format of pricing information may not align with the prohibition on information blocking and that well-intended exceptions to information blocking may overlap and require every health care provider to create new information blocking policies and procedures and significant documentation to justify the use of the exceptions.

Response: We thank commenters for this feedback. With respect to comments regarding cost reduction, we note that overall health care inflation was not the primary focus of our proposal. Step Five of the market-based MS–DRG relative weight methodology, as finalized, would normalize the relative weights by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration. As under the current cost-based relative weight estimation methodology, the normalization adjustment is intended to help ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

In regards to additional guidance on these remaining issues raised by commenters on high cost implantable devices and information blocking, we do not fully understand the commenters' concerns in the context of our proposed or final policies. Nevertheless, we remain open to continued conversations with commenters, and adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date and may provide additional reporting guidance as appropriate or as determined necessary. However, absent additional reporting guidance, we believe that hospitals have the capability to report this market based data to account for relative resource use by MS–DRG, for cost reporting periods ending on or after January 1, 2021.

For example, with respect to high cost implantable devices, if the commenter is requesting additional clarity on how negotiated charges for high-cost implantable devices should be accounted for within the median payer-specific negotiated charges by MS–DRG, as described earlier, since hospitals assign the underlying ICD–10–CM principal diagnosis, and any other secondary diagnosis codes and ICD–10–PCS procedure codes, which determine how patients are assigned to an MS–DRG, that hospitals are able to associate those items and services to MS–DRGs for each discharge. Additionally, hospitals that are not as familiar with MS–DRGs have access to the most current publically available version of the CMS Grouper used to group ICD–10 codes to MS–DRGs, and are able to use this software to uniformly group inpatient items and services to MS–DRGs, either initially by proactively using the same Grouper version used by CMS, or retrospectively after an inpatient hospital stay, but prior to submitting this information on the hospital cost report.

Final Action: After consideration of the comments received, and for the reasons previously discussed, we are finalizing our proposed market-based data collection requirement with a modification. Specifically, we are finalizing that hospitals would report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We are not finalizing the proposed requirement that hospitals report on the Medicare cost report the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, by MS–DRG. We are also not finalizing the collection of the alternative data collection measure, the median negotiated reimbursement amount, as discussed in the proposed rule. To determine the median payer-specific negotiated charge for MA organizations for a given MS–DRG, a hospital would follow the process as outlined in the proposed rule (85 FR 32794) and discussed previously in this final rule. We are finalizing our definitions of ''payer-specific negotiated charge,'' ''third party payer,'' ''MA organization'' and ''items and services,'' as proposed. For the purposes of calculating and reporting the median payer-specific negotiated charge the hospital has negotiated with all of its MA organization payers, by MS–DRG, we define an MA organization the same way as proposed, and defined in 42 CFR 422.2; namely, an MA organization means a public entity or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements. We note that the definition of third party payer, for the purposes of reporting median payer-specific negotiated charges set forth in this rule, includes MA organizations that have contracted with CMS.

We are finalizing our proposed amendment to the regulations to specify this data collection requirement at 42 CFR 413.20(d)(3), with modification, to require the collection of only the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations. This data collection requirement is effective for cost reporting periods ending on or after January 1, 2021. As stated in the

proposed rule, further instructions for the reporting of this market-based data collection requirement on the Medicare cost report will be discussed in a forthcoming revision of the Information Collection Request currently approved under OMB control number 0938–0050, expiration date March 31, 2022. We may provide additional guidance regarding this data collection policy as determined appropriate or necessary. However, absent additional guidance, we believe that hospitals have the capability to report this market-based data, as required, for cost reporting periods ending on or after January 1, 2021.

We are also finalizing the adoption of a market-based MS–DRG relative weight methodology effective for FY 2024. We are finalizing the market-based MS–DRG relative weight methodology, as described within the FY 2021 IPPS/LTCH PPS proposed rule, without modification. Specifically, we will begin using the median payer-specific negotiated charge by MS–DRG for MA organizations in the market-based MS–DRG relative weight methodology beginning with the relative weights calculated for FY 2024. We also remain open, as described in the proposed rule, to making modifications and refinements to this market-based methodology, through rulemaking prior to the FY 2024 effective date. We are not finalizing, at this time, a transition period to this market-based MS–DRG relative weight methodology, but may consider this in future rulemaking prior to FY 2024. We expect, for some period of time, following implementation of this market-based MS–DRG relative weight methodology, as discussed in the proposed rule, to continue to estimate and publicly provide the MS–DRG relative weights calculated using the cost-based estimation methodology for informational purposes.

We will continue to consider ways to reduce the role of hospital chargemasters in Medicare IPPS payments, as we described in the proposed rule, to further reflect market-based approaches in Medicare FFS payments, to the extent permitted by law.

V. Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2021

The annual update to the national capital Federal rate, as provided for in

42 CFR 412.308(c), for FY 2021 is discussed in section III. of the Addendum to this FY 2021 IPPS/LTCH PPS final rule.

In section II.D. of the preamble of this FY 2021 IPPS/LTCH PPS final rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are making for FY 2021, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not making a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

We also note that in section II.D.2.b. of the preamble of this final rule, we are finalizing new MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, and in section II.E.2.b. of this final rule, we are finalizing a modification to our relative weight methodology for new MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. In addition, in section IV.I. of the preamble of this final rule, we discuss our finalized adjustment to the payment amount for clinical trial cases or expanded access use immunotherapy that will group to new MS–DRG 018 for both operating IPPS payments and capital IPPS payments. We refer readers to section IV.I. of this preamble for additional details on the payment adjustment for these cases.

VI. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2021

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FYs 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50747 through 50748 and 79 FR 50156 through 50157, respectively), we adopted a policy of using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2014 and subsequent fiscal years for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. However, in the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent years. Accordingly, for FY 2021, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2021 percentage increase in the 2014-based IPPS operating market basket.

For the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32798), based on IGI's 2019 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2021 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, we stated that the FY 2021 rate-of-increase percentage that would be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we proposed that if more recent data became available for the final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2021. For this FY 2021 IPPS/LTCH PPS final rule, based on IGI's 2020 second quarter forecast, the 2014-based IPPS operating market basket update for FY 2021 is 2.4 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the FY 2021 rate-of-increase percentage that will be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.4 percent, in accordance with the applicable regulations at 42 CFR 413.40.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the

number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2021, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2021, the update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2021, which would be equal to the percentage increase in the hospital market basket index, which is estimated to be the percentage increase in the 2014-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the update to an extended neoplastic disease care hospital's target amount for FY 2021 is 2.4 percent, which is based on IGI's 2020 second quarter forecast. Furthermore, we proposed that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2021.

We did not receive comments in response to the proposals, as previously discussed. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing as proposed, without modification, our policy for updating the target amounts for excluded hospitals. As discussed previously, based on IGI's 2020 second quarter forecast, the FY 2021 rate-of-increase percentage that will be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.4 percent.

B. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, adjusting, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2019.

The table that follows includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2019. As indicated previously, the adjustments made during FY 2019 only pertain to cost reporting periods ending in years prior to FY 2019. Total adjustment payments made to IPPS-excluded hospitals during FY 2019 are $44,068,703. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Children's Hospitals	5	$9,145,476	$2,459,468
Cancer Hospitals	2	$63,425,853	$41,609,235
Total	**7**	**$72,571,329.00**	**$44,068,703**

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

a. Background and Overview

As discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under

section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limited participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 required the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, we released a request for applications (RFA) for the FCHIP demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RFA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016, and concluded on July 31, 2019. The selected CAHs were located in Montana, Nevada, and North Dakota, and participated in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701). Eight CAHs participated in the telehealth intervention, three CAHs participated in the skilled nursing facility/nursing facility bed intervention, and two CAHs participated in the ambulance services intervention. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention included in the RFA.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we finalized a policy to address the budget neutrality requirement for the demonstration. We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), but did not make any changes to the policy that was adopted in FY 2017. As explained in the FY 2017 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in Medicare payments as a result of the demonstration). However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we adopted in the FY 2017 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we will comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the FCHIP demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. For this FY 2021 IPPS/LTCH PPS final rule, we estimate that the total impact of the payment recoupment (if needed) will be no greater than 0.03 percent of CAHs' total Medicare payments (that is, Medicare Part A and Part B) within 1 fiscal year. The final budget neutrality estimates for the FCHIP demonstration will be based on costs incurred during the entire demonstration period, which is August 1, 2016, through July 31, 2019.

b. FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2021 IPPS/LTCH PPS proposed rule, our goal was to maintain the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments to the participating CAHs

resulting from the demonstration). The budget neutrality assessment will seek to determine if this goal has been met by examining expenditures for beneficiaries who received an intervention-related service(s) at a demonstration CAH or a comparison CAH. The demonstration and comparison groups will be identified as Medicare beneficiaries receiving an intervention-related service (that is, telemedicine, SNF/NF or ambulance) at participating CAHs and non-participating CAHs, respectively. To ensure that there is no cross contamination between the groups, the demonstration and comparison groups will be mutually exclusive so beneficiaries who received intervention-related services at both participating and non-participating CAHs will be included in the demonstration (intervention) group only. The analysis of budget neutrality will seek to identify both the costs related to providing the intervention-related services under the demonstration and any potential downstream effects of these services, including any savings that may have accrued.

We intend to incorporate two components into the budget neutrality analytical approach: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32800), we propose to estimate the cost of the demonstration for each fiscal year of the demonstration period using Medicare cost reports for the participating hospitals, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention related services.

First, using Medicare administrative claims and enrollment data, a difference-in-difference (DID) regression analysis will be used to compute the impact of the demonstration interventions on Medicare expenditures, relative to what expenditures would have looked like without the demonstration. The DID regression analysis will compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis will be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We will estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each demonstration performance year. While the majority of demonstration participants had cost reporting years that aligned with the demonstration period start date of July 1, 2016, several participating CAHs did not have cost reporting years that coincided with the demonstration start date. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, when a CAH's cost reporting year does not align with the timeframes used under the demonstration, additional calculations are necessary to carve-out data that relates to the portion of a cost reporting year when the demonstration was not in effect. We will determine the final budget neutrality results for the demonstration once complete data is available for the demonstration period. As we stated in the proposed rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration based on the data available to date, upon receiving data for the full demonstration period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

Under the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years. The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and minimize any impact on CAHs' operations. Under the policy adopted in FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped beginning in CY 2020. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32810), we stated that based on the currently available data, the determination of budget neutrality results is preliminary and the amount of any reduction to CAH payments that will be needed in order to recoup excess costs under the demonstration remains uncertain. Therefore, we proposed to revise the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment and stated that we will revisit this policy in rulemaking for FY 2022, when we expect to have complete data for the demonstration period. Since our data analysis is incomplete, it is not possible to determine the impact of this policy for any national payment system for FY 2021.

Comment: Commenters expressed support for our proposal to delay implementation of any budget neutrality adjustment until we have complete data.

Response: We acknowledge and appreciate the comments. After consideration of the public comments received, we are finalizing this proposal without modification.

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2021

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act (''subclause II'' LTCHs) also provided an alternative definition of LTCHs. However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage

adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 9821), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

We received several public comments that addressed issues, including the Coronavirus disease 2019 (COVID–19) pandemic, that were outside the scope of the FY 2021 IPPS/LTCH PPS proposed rule. We will keep these comments in mind and may consider them for future rulemaking.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the

Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide—all payer systems, subject to the—rate-of increase—test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).

- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2021

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 761 MS–DRG groupings. For FY 2021, there will be 767 MS–DRG groupings based on the changes, as discussed in section II.E. of the preamble of this final rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. Then we assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of this final rule, we provide a general summary of our existing methodology for determining the FY 2021 MS–LTC–DRG relative weights under the LTCH PPS.

As we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32803), in general, for FY 2021, we are continuing to use our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.B.3. of the preamble of this final rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, as we proposed, the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that

would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.B.3.c. of the preamble of this final rule). In addition, for FY 2021, as we proposed, we are continuing to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.B.3.c. of the preamble of this final rule.

Furthermore, for FY 2021, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, as we proposed, we are continuing to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we grouped all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we accounted for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we made adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.B.3.g. of the preamble of this final rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2021

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this final rule, as we proposed, we updated the MS–LTC–DRG classifications effective October 1, 2020 through September 30, 2021 (FY 2021), consistent with the changes to specific MS–DRG classifications presented in section II.F. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2021 presented in section II.F. of the preamble of this final rule are the same as the MS–DRGs that are being used under the IPPS for FY 2021. In addition, because the MS–LTC–DRGs for FY 2021 are the same as the MS–DRGs for FY 2021, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 38 as discussed in section II.E. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, also are applicable under the LTCH PPS for FY 2021.

3. Development of the FY 2021 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the MS–LTC–DRG Relative Weights for FY 2021

In this final rule, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32805), we are continuing to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2021, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our application of our existing methodology for determining the MS–LTC–DRG relative weights for FY 2021, and we discuss the effects of our policies concerning the data used to determine the FY 2021 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

We generally provide the low-volume quintiles and no-volume crosswalk data

previously published in Tables 13A and 13B for each annual proposed and final rule as one of our supplemental IPPS/LTCH PPS related data files that are made available for public use via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of IPPS Table 11 and to make it easier for the public to navigate and find the relevant data and information used for the development of proposed and final payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years (83 FR 41522). We refer readers to the CMS website for the low-volume quintiles and no-volume crosswalk data previously furnished via Tables 13A and 13B.

c. Data

For the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32805), consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2021, we obtained total charges from FY 2019 Medicare LTCH claims data from the December 2019 update of the FY 2019 MedPAR file, which was the best available data at that time, and we proposed to use Version 38 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we proposed that if more recent data become available, we would use those data and the finalized Version 38 of the GROUPER in establishing the FY 2021 MS–LTC–DRG relative weights in the final rule. Accordingly, for this final rule, we are establishing the FY 2021 MS–LTC–DRG relative weights based on updated FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 MedPAR file, which is the best available data at the time of development of this final rule, and used the finalized Version 38 of the GROUPER to classify LTCH cases.

To calculate the FY 2021 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, as we proposed, we continued to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2020 update of the FY 2019 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2019 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2019 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that, for purposes of developing the MS–LTC–DRG relative weights we have previously addressed the treatment of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals or for certain severe wound care discharges from certain LTCHs provided by sections 15009 and 15010 of Public Law 114–255, respectively. The temporary exception from the site neutral payment rate for certain spinal cord specialty hospitals is effective for discharges in cost reporting periods beginning during FYs 2018 and 2019, and the temporary exception from the site neutral payment rate for certain severe wound care discharges from certain LTCHs was effective for a discharge in cost reporting period beginning during FY 2018. These statutory provisions will no longer be in effect for any discharges occurring in FY 2021 (that is, an LTCH with a cost reporting period that begins on the last day of FY 2019, on September 30, 2019, would end on September 29, 2020, the day prior to the start of FY 2021 on October 1, 2020). Therefore, we no longer need to address the treatment of these cases for purposes of developing the MS–LTC–DRG relative weights for FY 2021 and subsequent years.

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the MS–LTC–DRG relative weights for FY 2021.

In summary, in general, we identified the claims data used in the development of the FY 2021 MS–LTC–DRG relative weights in this final rule, as we proposed, by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the dual payment rate structure been in effect. Finally, as we proposed, we trimmed the claims data of all-inclusive rate providers reported in the March 2020 update of the FY 2019 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2020 update of the FY 2019 MedPAR file, but, had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy. As we proposed, we used the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2021.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH

PPS, in this FY 2021 IPPS/LTCH PPS final rule, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32806), we continued to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2021. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2021, as we proposed, we continued to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. of the preamble of this final rule (Step 3) of the preamble of this final rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§§ 412.529 and 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of this final rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail in this final rule). For FY 2021, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32806), we are continuing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2021 MS–LTC–DRG relative weights.

In determining the FY 2021 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, as we proposed, we made adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.B.3.g. of the preamble of this final rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32807), we are continuing to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148).) In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, as we proposed, we made adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.B.3.g. (Step 6) of the preamble of this final rule.

In this final rule, based on the best available data (that is, the March 2020 update of the FY 2019 MedPAR files), we identified 251 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles, each containing at least 50 MS–LTC–DRGs (251/5 = 50 with a remainder of 1). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, as we proposed, we employed our historical methodology for determining which of the low-volume quintiles would contain the additional low-volume MS–LTC–DRG. Specifically for this final rule, because the average charge of the 151st low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 152nd low-volume MS–LTC–DRG (assigned to Quintile 4) than to the average charge of the 150th low-volume MS–LTC–DRG (assigned to Quintile 3), we assigned it to Quintile 4 (such that Quintile 4 contains 51 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed in this final rule). This resulted in 4 of the 5 low-volume quintiles containing 50 MS–LTC–DRGs (Quintiles 1, 2, 3, and 5) and 1 low-volume quintiles containing

51 MS–LTC–DRGs (Quintile 4). As discussed earlier, for this final rule, we are providing the list of the composition of the low-volume quintiles for low-volume MS–LTC–DRGs for FY 2021 in a supplemental data file for public use posted via the internet on the CMS website for this final rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

In order to determine the FY 2021 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, as we proposed, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in section VII.B.3.g. of the preamble of this final rule. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the FY 2021 MS–LTC–DRG Relative Weights

In this final rule, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32807), we are continuing to use our current methodology to determine the FY 2021 MS–LTC–DRG relative weights.

In summary, to determine the FY 2021 MS–LTC–DRG relative weights, as we proposed, we grouped applicable LTCH cases to the appropriate MS–LTC–DRG, while taking into account the low-volume quintiles (as described previously) and cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate MS–LTC–DRG (or low-volume quintile), as we proposed, we calculated the FY 2021 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2). Next, as we proposed, we adjusted the number of applicable LTCH cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases (Step 3). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1) and statistical outliers (Step 2), which are the SSO-adjusted applicable LTCH cases and corresponding charges (Step 3), as we proposed, we calculated ''relative adjusted weights'' for each MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the FY 2021 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2021 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the FY 2021 MS–LTC–DRG relative weights, as we proposed, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our calculation of the FY 2021 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we continued to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the FY 2021 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, as we proposed, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2021 MS–LTC–DRG relative weights would lower the FY 2021 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, as we proposed, we continued to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the FY 2021 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, as we proposed, we calculated the FY 2021 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2021 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 3 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 3 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a FY 2021 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the March 2020 update of the FY 2019 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, as we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this rule).

Of the 767 MS–LTC–DRGs for FY 2021, we identified 375 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. This number includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 347 MS–LTC–DRGs that for which, as we proposed, we assigned a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $375 - 11 - 2 - 15 = 347$). As we proposed, we assigned relative weights to each of the 347 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 392 ($767 - 375 = 392$) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2019 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 392 MS–LTC–DRGs to which we cross-walked each of the 347 ''no-volume'' MS–LTC–DRGs.) Then, as we generally proposed, we assigned the 347 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG. (As explained in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2020 update of the FY 2019 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2021, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2021. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2021. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

As discussed earlier, for this final rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2021 in a supplemental data file for public use

posted via the internet on the CMS website for this rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the relative weights for the FY 2021 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume MS–LTC–DRGs crosswalk information for FY 2021 (which, as previously stated, we are providing in a supplemental data file posted via the internet on the CMS website for this final rule).

Example: There were no trimmed applicable LTCH cases in the FY 2019 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.8730 for FY 2021 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, as we proposed, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2021, consistent with our historical relative weight methodology, as we proposed, we established a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, as we proposed, we established a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, as we proposed, we established a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we proposed, we established a relative weight 0.0000 for these 15 ''psychiatric or rehabilitation'' MS LTC DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate will not be applicable for any LTCH discharges occurring in FY 2021, and as such payment under the LTCH PPS will be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–DRGs.

Step 6—Adjust the FY 2021 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same

base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2021 MS–LTC–DRG relative weights, consistent with our historical methodology, as we proposed, we continued to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2021 MS–LTC–DRG relative weights in this final rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website.

Step 7—Calculate the FY 2021 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, as we proposed, we updated the MS–LTC–DRG classifications and relative weights for FY 2021 based on the most recent available LTCH data for applicable LTCH cases, and continued to apply a budget neutrality adjustment in determining the FY 2021 MS–LTC–DRG relative weights.

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we continued to use our established two-step budget neutrality methodology.

To calculate the normalization factor for FY 2021, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32811), we grouped applicable LTCH cases using the FY 2021 Version 38 GROUPER, and the recalibrated FY 2021 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2020 GROUPER Version 37 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2020 by the average CMI for FY 2021. That ratio is the normalization factor. Because the calculation of the normalization factor involves the relative weights for the MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume MS–LTC–DRGs are included in the calculation (and the MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the budget neutrality adjustment factor, we simulated estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2021 normalized relative weights and GROUPER Version 38; simulated estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2020 MS–LTC–DRG relative weights and the FY 2020 GROUPER Version 37; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2020 MS–LTC–DRG relative weights and the GROUPER Version 37 by the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2021 MS–LTC–DRG relative weights and the GROUPER Version 38. The resulting ratio is the budget neutrality adjustment factor. The calculation of the budget neutrality factor involves the relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume MS–LTC–DRGs or to MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases grouped to a MS–LTC–DRG with no applicable LTCH cases. (Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less), which are removed from the relative weight calculation in step 2 that are grouped to a MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the budget neutrality factor calculation).

In this final rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), as we proposed, we continued to use our established two-step budget neutrality methodology. Therefore, in this final rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2021, as we proposed, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2021 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Use the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2019 MedPAR file) and group them using the FY 2021 GROUPER (that is, Version 38 for FY 2021) and the recalibrated FY 2021 MS–LTC–DRG relative weights (determined in Steps 1 through 6 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2020 GROUPER (Version 37) and FY 2020 MS–LTC–DRG relative weights and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2021 (determined in Step 1.a.) by the average case-mix index for FY 2020 (determined in Step 1.b.). As a result, in determining the MS–LTC–DRG relative weights for FY 2021, each recalibrated MS–LTC–DRG relative weight is multiplied by the normalization factor of 1.25890 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculated a second budget neutrality

factor consisting of the ratio of estimated aggregate FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. stated previously) after reclassification and recalibration to estimated aggregate payments for FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. stated previously).

That is, for this final rule, for FY 2021, under the second step of the budget neutrality methodology, as we proposed, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2021 and GROUPER Version 38 (as described previously); (2.b.) simulate estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2020 GROUPER (Version 37) and the FY 2020 MS–LTC–DRG relative weights in Table 11 of the FY 2020 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2021 MS–LTC–DRG relative weights, each normalized relative weight is then multiplied by a budget neutrality factor of 0.9995082 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the FY 2021 MS–LTC–DRG relative weights in this final rule, consistent with our existing methodology, as we proposed, we applied a normalization factor of 1.25890 and a budget neutrality factor of 0.9995082. Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2021.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2021

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we used to update the LTCH PPS standard Federal payment rate for FY 2021, that is, effective for LTCH discharges occurring on or after October 1, 2020 through September 30, 2021. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under § 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2021 IPPS/LTCH PPS final rule, we present our policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2021.

The update to the LTCH PPS standard Federal payment rate for FY 2021 is presented in section V.A. of the Addendum to this rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2021 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2021 as required by the statute (as discussed in section VII.C.2.c. of the preamble of this final rule). As we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32812), we also made an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2021 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).

In addition, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41532 through 41537), we eliminated the 25-percent threshold policy in a budget neutral manner. The budget neutrality requirements are codified in the regulations at § 412.523(d)(6). Under these regulations, a temporary, one-time factor is applied to the standard Federal payment rate in FY 2019 and FY 2020, and a permanent, one-time factor in FY 2021. These factors as established in the correction to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41536) are—

- For FY 2019, a temporary, one-time factor of 0.990878;
- For FY 2020, a temporary, one-time factor of 0.990737; and
- For FY 2021 and subsequent years, a permanent, one-time factor of 0.991249.

Therefore, in determining the FY 2021 LTCH PPS standard Federal payment rate, as we proposed, we—

- Removed the temporary, one-time factor of 0.990737 for the estimated cost of the elimination of the 25-percent threshold policy in FY 2020 by applying a factor of (1/0.990737);
- Applied a permanent, one-time factor of 0.991249 for the estimated cost of the elimination of the 25-percent threshold policy in FY 2021;

2. FY 2021 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017 (81 FR 57100 through 57102). As discussed in section VII.D. of the preamble of this final rule, as we proposed, we are rebasing and revising the 2013-based LTCH market basket to reflect a 2017 base year. For additional details on the historical development of the market basket used under the LTCH

PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2013-based LTCH market basket, we refer readers to section VII.D. of the preamble of the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25153 through 25167 and 81 FR 57086 through 57099, respectively).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2021

CMS has used an estimated market basket increase to update the LTCH PPS. As previously noted, for FY 2021 we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. As we proposed, we used data from cost reports beginning in FY 2017 because these data are the latest available complete data at the time of rulemaking for purposes of calculating cost weights for the market basket. We believe that the 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs, as discussed in greater detail in section VII.D. of the preamble of this final rule. In this final rule, as we proposed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32812—32813), we used the 2017-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2021.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A). Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the multifactor productivity (MFP) adjustment''). Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2021.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at § 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this final rule.)

d. Annual Market Basket Update Under the LTCH PPS for FY 2021

Consistent with our historical practice and our proposal, we estimate the market basket increase and the MFP adjustment based on IGI's forecast using the most recent available data. In the proposed rule (85 FR 32813), we proposed to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2021 of 2.5 percent based on the best available data at that time (that is, the estimated LTCH PPS market basket increase of 2.9 percent less the MFP adjustment of 0.4 percentage point). Consistent with our historical practice, we also proposed to use a more recent estimate of the market basket and the MFP adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2021.

For this final rule, based on IGIs second-quarter 2020 forecast, the FY 2021 full market basket estimate for the LTCH PPS using the 2017-based LTCH market basket is 2.3 percent. We note that the fourth quarter 2019 forecast used for the proposed market basket update was developed prior to the economic impacts of the COVID–19 pandemic. This lower update (2.3 percent) for FY 2021, relative to the proposed rule (2.9 percent), is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.

For FY 2021, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. (We note that sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act required an additional reduction each year only for FYs 2010 through 2019.) (For additional details on our established methodology

for adjusting the market basket increase by the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed a MFP adjustment of 0.4 percentage point based on IGIs fourth quarter 2019 forecast. Based on the more recent data available for this final rule, the current estimate of the 10-year moving average growth of MFP for FY 2021 is -0.1 percentage point. This MFP is based on the most recent macroeconomic outlook from IGI at the time of rulemaking (released June 2020) in order to reflect more current historical economic data. IGI produces monthly macroeconomic forecasts, which include projections of all of the economic series used to derive MFP. In contrast, IGI only produces forecasts of the more detailed price proxies used in the LTCH market basket on a quarterly basis. Therefore, IGI's second quarter 2020 forecast is the most recent forecast of the LTCH market basket update.

We note that it has typically been our practice to base the projection of the market basket price proxies and MFP in the final rule on the second quarter IGI forecast. For this final rule, we are using the IGI June macroeconomic forecast for MFP because it is a more recent forecast, and it is important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. Historically, the MFP adjustment based on the second quarter IGI forecast has been very similar to the MFP adjustment derived with IGI's June macroeconomic forecast. Substantial changes in the macroeconomic indicators in between monthly forecasts are atypical.

Given the unprecedented economic uncertainty as a result of the COVID–19 pandemic, the changes in the IGI macroeconomic series used to derive MFP between the second quarter 2020 IGI forecast and the IGI June 2020 macroeconomic forecast is significant. Therefore, we believe it is technically appropriate to use IGI's more recent June 2020 macroeconomic forecast to determine the MFP adjustment for the final rule as it reflects more current historical data. For comparison purposes, the 10-year moving average growth of MFP for FY 2021 is projected to be -0.1 percentage point based on IGI's June 2020 macroeconomic forecast compared to a FY 2021 projected 10-year moving average growth of MFP of 0.7 percentage point based on IGI's second quarter 2020 forecast. Mechanically subtracting the negative 10-year moving average growth of MFP from the market basket percentage increase using the data from the IGI June 2020 macroeconomic forecast would have resulted in a 0.1 percentage point increase in the FY 2021 annual update to the LTCH PPS standard Federal payment rate. However, under section 1886(m)(3)(A)(i) of the Act, the Secretary is required to reduce (not increase) any annual update to the LTCH PPS standard Federal payment rate by 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity. Accordingly, we will be applying a 0.0 percentage point MFP adjustment to the market basket update. Therefore, the annual market basket update to the LTCH PPS standard Federal payment rate for FY 2021 is 2.3 percent (that is, the FY 2021 full market basket estimate for the LTCH PPS with 0.0 percentage point adjustment made for MFP).

For FY 2021, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the 2.3 percent annual market basket update to the LTCH PPS standard Federal payment rate for FY 2021 will be reduced by 2.0 percentage points required by section 1886(m)(5) of the Act.

In this FY 2021 IPPS/LTCH PPS final rule, in accordance with the statute, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with our proposal, we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2021 of 2.3 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.3 percent less the MFP adjustment of 0.0 percentage point).

While we have historically implemented the payment updates to the LTCH PPS in individual amendments to the regulations, given existing statutory provisions affecting the LTCH update are constant going forward, in the proposed rule we proposed to revise § 412.523(c)(3) by adding a new paragraph (xvii), which would specify that the LTCH PPS standard Federal payment rate for FY 2021 and subsequent fiscal years is the LTCH PPS standard Federal payment rate for the previous LTCH PPS payment year updated by the market basket (as determined by CMS), less a multifactor productivity adjustment (as determined by CMS), and further adjusted, as appropriate, as described in § 412.523(d) (including the application of the adjustment factor for the cost of the elimination of the 25-percent threshold policy under § 412.523(d)(6) as previously discussed) rather than codifying specific numerical updates annually as was our historical practice. For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xvi) in conjunction with § 412.523(c)(4), we proposed to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act.

We did not receive any comments on this proposal. Therefore we are finalizing it as proposed without modification. Accordingly, as we proposed, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 0.3 percent (that is, 2.3 percent minus 2.0 percentage points) for FY 2021 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. We note that, consistent with historical practice, as we proposed, we adjusted the FY 2021 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this final rule).

D. Rebasing and Revising of the LTCH Market Basket

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the ''excluded hospital with capital'' market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that mix. Accordingly, the term ''market basket,'' as used in this section, refers to an input price index.

Beginning with rate year (RY) 2007, LTCH PPS payments were updated using a 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We

excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at 42 CFR 413.40. Those types of hospitals are not paid under a PPS. Also, the 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the 2002-based RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the 2002-based RPL market basket by creating and implementing a 2008-based RPL market basket. We also discussed the creation of a stand-alone LTCH market basket and received several public comments, all of which supported deriving a standalone LTCH market basket (76 FR 51756 through 51757). In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of a stand-alone 2009-based LTCH-specific market basket that reflects the cost structures of LTCHs only (77 FR 53467 through 53479). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57099), we finalized the rebasing and revising of the 2009-based LTCH market basket to reflect a 2013 base year (the 2013-based LTCH market basket).

For FY 2021, we proposed to rebase and revise the 2013-based LTCH market basket to reflect a 2017 base year (85 FR 32814). The proposed 2017-based LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and before October 1, 2017. We proposed to use data from cost reports beginning in FY 2017 because these data are the latest available complete data for purposes of calculating cost weights for the market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed LTCH market basket, describe the proposed methodologies for developing the operating and capital portions of the 2017-based LTCH market basket, and provide information on the proposed price proxies. We then describe any comments received, responses to these comments, and our final policies for this final rule.

2. Overview of the 2017-Based LTCH Market Basket

Similar to the 2013-based LTCH market basket, the proposed 2017-based LTCH market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (in the proposed rule, we proposed to use 2017 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

3. Development of the 2017-Based LTCH Market Basket Cost Categories and Weights

We invited public comments on our proposed methodology, discussed in this section of this rule, for deriving the proposed 2017-based LTCH market basket.

a. Use of Medicare Cost Report Data

We proposed a 2017-based LTCH market basket that consists of seven major cost categories and a residual derived from the 2017 Medicare cost reports (CMS Form 2552–10, OMB Control Number 0938–0050) for LTCHs. The seven cost categories are Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Home Office/Related Organization Contract Labor, and Capital. The residual category reflects all remaining costs not captured in the seven cost categories. The 2013-based LTCH market basket did not use the Medicare cost reports to calculate the Home Office/Related Organization Contract Labor cost weight.

Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer. Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we proposed to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay (LOS) that is within a comparable range of their total facility average LOS. We define the Medicare average LOS based on data reported on the Medicare cost report (CMS Form 2552–10, OMB Control Number 0938–0050) Worksheet S–3, Part I, line 14. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs for Medicare covered days as our proposed edit excludes those LTCHs that had an average total facility LOS that was much different than the average Medicare LOS. For the 2013-based LTCH market basket, we used the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital. Based on our analysis of the 2017 Medicare cost reports, for the proposed 2017-based LTCH market basket, we proposed to again use the cost reports submitted by LTCHs with

Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital. The universe of LTCHs had an average Medicare LOS of 26 days, an average total facility LOS of 31 days, and aggregate Medicare utilization (as measured by Medicare inpatient LTCH days as a percentage of total facility inpatient LTCH days) of 49 percent in 2017. Applying the proposed trim excludes 9 percent of LTCH providers and results in a subset of LTCH Medicare cost reports with an average Medicare LOS of 25 days, average facility LOS of 27 days, and aggregate Medicare utilization (based on days) of 58 percent. The 9 percent of providers that are excluded from the proposed 2017-based LTCH market basket had an average Medicare LOS of 27 days, average facility LOS of 70 days, and aggregate Medicare utilization of 15 percent.

We proposed to use the cost reports for LTCHs that meet this requirement to calculate the costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office/Related Organization Contract Labor, and Capital) for the market basket. For comparison, the 2013-based LTCH market basket utilized the Bureau of Economic Analysis Benchmark Input-Output data rather than Medicare cost report data to derive the Home Office/Related Organization Contract Labor cost weight. A more detailed discussion of this methodological change is provided in section VII.D.3.a.(6). of the preamble of this final rule.

(1) Wages and Salaries Costs

We proposed to derive Wages and Salaries costs as the sum of routine inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, column 1. Because overhead salary costs are attributable to the entire LTCH, we proposed to only include the proportion attributable to the Medicare allowable cost centers. For the 2017-based LTCH market basket, we proposed that routine and ancillary Wages and Salaries costs would be equal to salary costs as reported on Worksheet A, column 1, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91, and 93. Then, we proposed to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of these routine and ancillary Wages and Salaries to total salaries (Worksheet A, column 1, line 200) times total overhead salaries (Worksheet A, column 1, lines 4 through 18). A similar methodology was used to derive Wages and Salaries costs in the 2013-based LTCH market basket.

(2) Employee Benefits Costs

Similar to the 2013-based LTCH market basket, we proposed to calculate Employee Benefits costs using Worksheet S–3, part II data. Specifically, we proposed to use data from Worksheet S–3, part II, column 4, lines 17, 18, 20, and 22, to derive Employee Benefits costs. The completion of Worksheet S–3, part II is only required for IPPS hospitals. For 2017, we found that approximately 20 percent of LTCHs voluntarily reported these data, which has fallen from the roughly 35 percent that reported these data for 2013. Our analysis of the Worksheet S–3, part II data submitted by these LTCHs indicates that we continue to have a large enough sample to enable us to produce a reasonable Employee Benefits cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we proposed to use Worksheet S–3, part II data (as was done for the 2013-based LTCH market basket) to calculate the Employee Benefits cost weight in the proposed 2017-based LTCH market basket.

We note that, effective with the implementation of CMS Form 2552–10, OMB Control Number 0938–0050, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part V, which is applicable to LTCHs. However, approximately 17 percent of LTCHs reported data on Worksheet S–3, part V for 2017, with most of these providers also reporting data on Worksheet S–3, part II. Because a greater percentage of LTCHs continue to report data on Worksheet S–3, part II than Worksheet S–3, part V for 2017, we did not propose to use the Employee Benefits and Contract Labor data reported on Worksheet S–3, part V to calculate the Employee Benefits cost weight in the proposed 2017-based LTCH market basket. We continue to encourage all providers to report these data on Worksheet S–3, Part V.

(3) Contract Labor Costs

Contract Labor costs are primarily associated with direct patient care services. Contract Labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described in this section of this final rule. Approximately 44 percent of LTCHs voluntarily reported Contract Labor costs on Worksheet S–3, part II, which was similar to the percentage obtained from 2013 Medicare cost reports. Only about 18 percent of LTCHs reported Contract Labor costs data on Worksheet S–3, part V.

As was done for the 2013-based LTCH market basket, we proposed to derive the Contract Labor costs for the proposed 2017-based LTCH market basket using voluntarily reported data from Worksheet S–3, part II. Our analysis of these data indicates that we have a large enough sample to enable us to produce a reasonable Contract Labor cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we proposed to use data from Worksheet S–3, part II, column 4, lines 11 and 13 to calculate the Contract Labor cost weight in the proposed 2017-based LTCH market basket.

(4) Pharmaceuticals Costs

We proposed to calculate Pharmaceuticals costs using nonsalary costs for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73). We proposed to estimate these costs using total pharmaceutical costs reported on Worksheet B, part I, column 0, lines 15 and 73 and then removing a portion of these costs attributable to salaries. We proposed to estimate the proportion of costs for removal as Worksheet A, column 1, lines 15 and 73 divided by the sum of Worksheet A, columns 1 and 2, lines 15 and 73. A similar methodology was used for the 2013-based LTCH market basket.

(5) Professional Liability Insurance Costs

We proposed that Professional Liability Insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses and self-insurance costs reported on Worksheet S–2, part I, columns 1 through 3, line 118. A similar methodology was used for the 2013-based LTCH market basket.

(6) Home Office/Related Organization Contract Labor Costs

For the 2017-based LTCH market basket, we proposed to determine the Home Office/Related Organization Contract Labor costs using Medicare

cost report data. Specifically, we proposed to calculate the Home Office/Related Organization Contract Labor costs using data reported on Worksheet S–3, part II, column 4, lines 14, 1401, 1402, 2550, and 2551 for those LTCH providers reporting total salaries on Worksheet S–3, part II, line 1.

The 2013-based LTCH market basket used the 2007 Benchmark Input-Output (I–O) expense data published by the Bureau of Economic Analysis (BEA) to derive these costs (81 FR 57089). A more detailed explanation of the general methodology using the BEA I–O data is provided in section VII.D.3.c. of the preamble of this final rule. We calculated the Home Office/Related Organization Contract Labor cost weight using expense data for North American Industry Classification System (NAICS) code 55, Management of Companies and Enterprises (81 FR 57098). We believe the proposed methodology for the 2017-based LTCH market basket is a technical improvement over the prior methodology because it represents more recent data that is representative compositionally and geographically of LTCHs.

(7) Capital Costs

We proposed that Capital costs be equal to Medicare allowable capital costs as reported on Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93. A similar methodology was used for the 2013-based LTCH market basket.

b. Final Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we proposed to trim the data for outliers. For each of the seven major cost categories, we first proposed to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of LTCH providers. For the 2017-based LTCH market basket (similar to the 2013-based LTCH market basket), we proposed that total Medicare allowable costs would be equal to the total costs as reported on Worksheet B, part I, column 26, lines 30 through 35, 50 through 76 (excluding 52, 61 and 75), 90 through 91, and 93.

For the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, and Capital cost weights, after excluding cost weights that are less than or equal to zero, we proposed to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider specific derived cost weights to ensure the exclusion of outliers. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We proposed to divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2017-based LTCH market basket for the given category. This trimming process is done for each cost weight separately.

For the Home Office/Related Organization Contract Labor cost weight, we proposed to apply a 1-percent top only trimming methodology. This allows all providers' Medicare allowable costs to be included, even if their Home Office/Related Organization Contract Labor costs were zero. We believe, as the Medicare cost report data (Worksheet S–2, part I, line 140) indicate, that not all LTCHs have a home office. LTCHs without a home office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Employee Benefits cost weights. Alternatively, LTCHs without a home office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All Other'' cost weight. We believe this 1-percent top-only trimming methodology is appropriate as it addresses outliers while allowing providers with zero Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation. If we applied both the top and bottom 5 percent trimming methodology, we would exclude providers who have zero Home Office/Related Organization Contract Labor costs.

Finally, we proposed to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed.

We received no comments on the proposed methodology to derive the major cost weights using the Medicare cost reports and therefore are finalizing this methodology without modification. We refer readers to Table E1 for the resulting proposed and final cost weights for these major cost categories.

TABLE E1—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Major Cost Categories	Proposed and Final 2017-Based LTCH Market Basket (Percent)	2013-Based LTCH Market Basket (Percent)
Wages and Salaries	42.6	41.5
Employee Benefits	6.2	6.5
Contract Labor	4.4	5.9
Professional Liability Insurance (Malpractice)	0.5	0.9
Pharmaceuticals	6.2	7.6
Home Office/Related Organization Contract Labor	1.9	N/A
Capital	9.9	9.7
All Other	28.3	27.8

The Wages and Salaries cost weight calculated from the Medicare cost reports for the 2017-based LTCH market basket is approximately 1 percentage point higher than the Wages and Salaries cost weight for the 2013-based LTCH market basket, while the Contract Labor cost weight is 1.5 percentage point lower. The 2017-based Pharmaceuticals cost weight also is roughly 1.5 percentage point lower than the cost weight for the 2013-based LTCH market basket.

As we did for the 2013-based LTCH market basket, we proposed to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that Contract Labor costs are comprised of both Wages and Salaries and Employee Benefits. The Contract Labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This rounded percentage is 87 percent. Therefore, we proposed to allocate 87 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 13 percent to the Employee Benefits cost weight.

We received no comments on the proposed methodology to allocate the Contract Labor cost weight to the Wages and Salaries cost weight and Employee Benefits cost weight and therefore, are finalizing this methodology without modification. We refer readers to Table E2 that shows the proposed and final Wages and Salaries and Employee Benefits cost weights after Contract Labor cost weight allocation for both the 2017-based LTCH market basket and the 2013-based LTCH market basket.

TABLE E2- WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major Cost Categories	Proposed and Final 2017-Based LTCH Market Basket	2013-Based LTCH Market Basket
Wages and Salaries	46.4	46.6
Employee Benefits	6.8	7.3
Compensation	53.2	53.9

After the allocation of the Contract Labor cost weight, the 2017-based Wages and Salaries cost weight is 0.2 percentage point lower and the Employee Benefits cost weight is 0.5 percentage point lower, relative to the respective cost weights for the 2013-based LTCH market basket. As a result, in the 2017-based LTCH market basket, the compensation cost weight is 0.7 percentage point lower than the Compensation cost weight for the 2013-based LTCH market basket.

c. Derivation of the Detailed Operating Cost Weights

To further divide the residual ''All Other'' cost weight estimated from the 2017 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following website: *https://www.bea.gov/industry/input-output-accounts-data*. For the 2013-based LTCH market basket, we used the 2007 Benchmark I–O data, the most recent data available at the time (81 FR 57089).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[451] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2012 Benchmark I–O data forward to 2017 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeated this practice for each year. Then, we calculated the cost shares that each cost category represents of the 2012 data inflated to 2017. These resulting 2017 cost shares were applied to the residual ''All Other'' cost weight to obtain the detailed cost weights for the proposed 2017-based LTCH market basket. For example, the cost for Food: Direct Purchases represents 4.9 percent of the sum of the residual ''All Other'' 2012 Benchmark I–O Hospital Expenditures inflated to 2017. Therefore, the Food: Direct Purchases cost weight represents 4.9 percent of the proposed 2017-based LTCH market basket's residual ''All Other'' cost category (28.3 percent), yielding a ''final'' Food: Direct Purchases proposed cost weight of 1.4 percent in the proposed 2017-based LTCH market basket (0.049×28.3 percent = 1.4 percent).

Using this methodology, we proposed to derive 17 detailed LTCH market basket cost category weights from the 2017-based LTCH market basket residual ''All Other'' cost weight (28.3 percent). These categories are: (1) Electricity; (2) Fuel, Oil, and Gasoline; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10) Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12) Installation, Maintenance, and Repair Services; (13) All Other Labor-Related Services; (14) Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17) All Other Nonlabor-Related Services. We note that for the 2013-based LTCH market basket, we had a Water and Sewerage cost weight. For the 2017-based LTCH market basket, we proposed to include Water and

[451] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

Sewerage costs in the Electricity cost weight due to the small amount of costs in this category.

For the 2013-based LTCH market basket, we used the I–O data for NAICS 55 Management of Companies to derive the Home Office/Related Organization Contract Labor cost weight, which were classified in the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost weights. As previously discussed, we proposed to use the Medicare cost report data to derive the Home Office/Related Organization Contract Labor cost weight, which we would further classify into the Professional Fees: Labor-related or Professional Fees: Nonlabor-related categories which we discuss in section VII.D.6. of the preamble of this final rule.

We received no comments on the proposed methodology to derive the detailed operating cost weights and therefore are finalizing this methodology without modification.

d. Derivation of the Detailed Capital Cost Weights

As described in section VII.D.3.b. of the preamble of this final rule, we proposed a Capital-related cost weight of 9.9 percent as calculated from the 2017 Medicare cost reports for LTCHs after applying the proposed trims as previously described. We proposed to then separate this total Capital-related cost weight into more detailed cost categories. Using 2017 Medicare cost reports, we are able to group Capital-related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs, as shown in Table E3. For each of these categories, we proposed to determine what proportion of total Capital-related costs the category represents using the data reported by the LTCH on Worksheet A–7, which is the same methodology used for the 2013-based LTCH market basket.

We also proposed to allocate lease costs across each of the remaining detailed Capital-related cost categories as was done in the 2013-based LTCH market basket. This would result in three primary Capital-related cost categories in the proposed 2017-based LTCH market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2017-based LTCH market basket. Rather, we proposed to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of Capital-related costs in general. As was done for the 2013-based LTCH market basket, we proposed to assume that 10 percent of the lease costs as a proportion of total Capital-related costs (63.0 percent) represents overhead and to assign those costs to the Other Capital-Related cost category accordingly. Therefore, we are assuming that approximately 6.3 percent (63.0 percent $\times$ 0.1) of total Capital-related costs represent lease costs attributable to overhead, and we proposed to add this 6.3 percentage points to the 6.7 percent Other Capital-Related cost category weight. We are also proposing to distribute the remaining lease costs (56.7 percent, or 63.0 percent less 6.3 percentage points) proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). For example, the Other Capital-Related cost category represented 18.2 percent of all three cost categories (Depreciation, Interest, and Other Capital-Related) prior to any lease expenses being allocated. This 18.2 percent is applied to the 56.7 percent of remaining lease expenses so that another 10.3 percentage points of lease expenses as a percent of total Capital-related costs is allocated to the Other Capital-Related cost category. Therefore, the resulting proposed Other Capital-Related cost weight is 23.3 percent (6.7 percent + 6.3 percent + 10.3 percent). This is the same methodology used for the 2013-based LTCH market basket. The proposed allocation of these lease expenses are shown in Table E3.

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also proposed to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For profit.

To disaggregate the Depreciation cost weight, we needed to determine the percent of total depreciation costs for LTCHs (after the allocation of lease costs) that are attributable to Building and Fixed equipment, which we hereafter refer to as the ''fixed percentage.'' We proposed to use depreciation and lease data from Worksheet A–7 of the 2017 Medicare cost reports, which is the same methodology used for the 2013-based LTCH market basket. Based on the 2017 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 44 percent of total depreciation costs, while depreciation costs for movable equipment account for 56 percent of total depreciation costs. As previously mentioned, we proposed to allocate lease expenses among the Depreciation, Interest, and Other Capital-Related cost categories. We determined that leasing building and fixed equipment expenses account for 88 percent of total leasing expenses, while leasing movable equipment expenses account for 12 percent of total leasing expenses. We proposed to sum the depreciation and leasing expenses for building and fixed equipment, as well as sum the depreciation and leasing expenses for movable equipment. This results in the proposed Building and Fixed Equipment Depreciation cost weight (after leasing costs are included) representing 76 percent of total depreciation costs and the Movable Equipment Depreciation cost weight (after leasing costs are included) representing 24 percent of total depreciation costs.

To disaggregate the Interest cost weight, we determine the percent of total interest costs for LTCHs that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. We proposed to use interest costs data from Worksheet A–7 of the 2017 Medicare cost reports for LTCHs, which is the same methodology used for the 2013-based LTCH market basket. The nonprofit percentage determined using this method is 21 percent.

We received no comments on the proposed methodology to derive the detailed capital cost weights and therefore are finalizing this methodology without modification. Table E3 provides the proposed and final detailed capital cost shares obtained from the Medicare cost reports. Ultimately, these detailed capital cost shares are applied to the total Capital-related cost weight determined in section VII.D.3.b. of the preamble of this final rule to separate the total Capital-related cost weight of 9.9 percent into more detailed cost categories and weights.

TABLE E3--CAPITAL COST SHARE COMPOSITION FOR THE PROPOSED AND FINAL 2017-BASED LTCH MARKET BASKET

	Capital Cost Share Composition Before Lease Expense Allocation (Percent)	Capital Cost Share Composition After Lease Expense Allocation (Percent)
Depreciation	**22**	**56**
Building and Fixed Equipment	17	42
Movable Equipment	5	14
Interest	**8**	**21**
Government/Nonprofit	2	4
For Profit	6	17
Lease	*63*	*N/A*
Other	**7**	**23**

Note: Detail may not add to total due to rounding.

e. 2017-Based LTCH Market Basket Cost Categories and Weights

Table E4 shows the cost categories and weights for the proposed and final 2017-based LTCH market basket compared to the 2013-based LTCH market basket.

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TABLE E4--PROPOSED AND FINAL 2017-BASED LTCH MARKET BASKET COST WEIGHTS COMPARED TO 2013-BASED LTCH MARKET BASKET COST WEIGHTS

Cost Category	Proposed and Final 2017-based LTCH Market Basket Cost Weight	2013-based LTCH Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**53.2**	**53.9**
Wages and Salaries	46.4	46.6
Employee Benefits	6.8	7.3
Utilities	**1.9**	**2.2**
Electricity	1.3	1.0
Fuel, Oil, and Gasoline	0.6	1.1
Water & Sewerage	n/a	0.1
Professional Liability Insurance	**0.5**	**0.9**
Malpractice	0.5	0.9
All Other Products and Services	**34.4**	**33.2**
All Other Products	**15.6**	**16.3**
Pharmaceuticals	6.2	7.6
Food: Direct Purchases	1.4	1.8
Food: Contract Services	1.6	1.1
Chemicals	0.5	0.7
Medical Instruments	3.6	2.4
Rubber & Plastics	0.5	0.6
Paper and Printing Products	0.8	1.2
Miscellaneous Products	1.1	0.8
All Other Services	**18.9**	**16.9**
Labor-Related Services	**9.7**	**8.3**
Professional Fees: Labor-related	4.5	3.5
Administrative and Facilities Support Services	0.9	0.9
Installation, Maintenance, and Repair	2.1	2.0
All Other: Labor-related Services	2.3	1.9
Nonlabor-Related Services	**9.1**	**8.6**
Professional Fees: Nonlabor-related	5.9	3.6
Financial services	1.2	2.9
Telephone Services	0.4	0.7
All Other: Nonlabor-related Services	1.6	1.4
Capital-Related Costs	**9.9**	**9.7**
Depreciation	**5.5**	**5.3**
Building and Fixed Equipment	4.2	3.9
Movable Equipment	1.3	1.4
Interest Costs	**2.1**	**2.4**
Government/Nonprofit	0.4	0.5
For Profit	1.6	1.8
Other Capital-Related Costs	**2.3**	**2.0**

Note: Totals may not sum due to rounding.

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4. Selection of Price Proxies

After developing the proposed cost weights for the 2017-based LTCH market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on U.S. Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies

for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

• *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).

• *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

• *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

• *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

• *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

• *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe that the CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table E7 lists all price proxies that we proposed to use for the 2017-based LTCH market basket. In this section of this rule is a detailed explanation of the price proxies we proposed for each cost category weight.

a. Price Proxies for the Operating Portion of the 2017-Based LTCH Market Basket

(1) Wages and Salaries

We proposed to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code CIU1026220000000I) to measure the wage rate growth of this cost category. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(2) Employee Benefits

We proposed to continue to use the ECI for Total Benefits for All Civilian workers in Hospitals to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for All Civilian workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(3) Electricity

We proposed to continue to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(4) Fuel, Oil, and Gasoline

Similar to the 2013-based LTCH market basket, for the 2017-based LTCH market basket, we proposed to use a blend of the PPI Industry for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark I–O data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that Petroleum Refineries expenses account for approximately 90 percent and Natural Gas expenses account for approximately 10 percent of Hospitals' (NAICS 622000) total Fuel, Oil, and Gasoline expenses. Therefore, we proposed to use a blend of 90 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2013-based LTCH market basket used a 70/30 blend of these price proxies, reflecting the 2007 I–O data (81 FR 57092). We believe that these two price proxies continue to be the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the 2017-based LTCH market basket.

(5) Professional Liability Insurance

We proposed to continue to use the CMS Hospital Professional Liability Index as the price proxy for PLI costs in the proposed 2017-based LTCH market basket. To generate this index, we collect commercial insurance medical liability premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2013-based LTCH market basket (81 FR 57092).

(6) Pharmaceuticals

We proposed to continue to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57092).

(7) Food: Direct Purchases

We proposed to continue to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(8) Food: Contract Purchases

We proposed to continue to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57092).

(9) Chemicals

Similar to the 2013-based LTCH market basket, we proposed to use a four-part blended PPI as the proxy for the chemical cost category in the 2017-based LTCH market basket. The proposed blend is composed of the PPI Industry for Industrial Gas Manufacturing, Primary Products (BLS

series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). We note that the four part blended PPI used in the 2013-based LTCH market basket is composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561–). For the 2017-based LTCH market basket, we proposed to derive the weights for the PPIs using the 2012 Benchmark I–O data. The 2013-based LTCH market basket used the 2007 Benchmark I–O data to derive the weights for the four PPIs (81 FR 57092).

We note that in the 2012 I–O data, the share of total chemicals expenses that the Soap and Cleaning Compound Manufacturing (NAICS 325610) represents decreased relative to the 2007 I–O data (from 5 percent to 2 percent), while the share of the total chemicals expenses that the All Other Chemical Product and Preparation manufacturing (NAICS 3259A0) categories represents increased (from 5 percent to 7 percent). As a result, we proposed to remove the PPI Industry for Soap and Cleaning Compound Manufacturing from the proposed blend for the 2017-based LTCH market basket and replace it with the PPI Industry for Other Miscellaneous Chemical Product Manufacturing.

We did not receive comments on the proposed methodology to derive the blended Chemicals price proxy using the 2012 Benchmark I–O and therefore are finalizing this methodology without modification. Table E5 shows the weights for each of the four PPIs used to create the proposed and final blended Chemical proxy for the 2017-based LTCH market basket compared to the 2013-based blended Chemical proxy.

TABLE E5: BLENDED CHEMICAL PPI WEIGHTS

Name	Proposed and Final 2017-based LTCH Weights (Percent)	2013-based LTCH Weights (Percent)	NAICS
PPI Industry for Industrial Gas Manufacturing	19	32	325120
PPI Industry for Other Basic Inorganic Chemical Manufacturing	13	17	325180
PPI Industry for Other Basic Organic Chemical Manufacturing	60	45	325190
PPI Industry for Soap and Cleaning Compound Manufacturing	n/a	6	325610
PPI Industry for Other Miscellaneous Chemical Product Manufacturing	8	n/a	325998

(10) Medical Instruments

We proposed to continue to use a blend of two PPIs for the Medical Instruments cost category. The 2012 Benchmark I–O data shows an approximate 57/43 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we proposed a blend composed of 57 percent of the commodity-based PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562) and 43 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563). The 2013-based LTCH market basket used a 50/50 blend of these PPIs based on the 2007 Benchmark I–O data (81 FR 57093).

(11) Rubber and Plastics

We proposed to continue to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(12) Paper and Printing Products

We proposed to continue to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(13) Miscellaneous Products

We proposed to continue to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(14) Professional Fees: Labor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(15) Administrative and Facilities Support Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(16) Installation, Maintenance, and Repair Services

We proposed to continue to use the ECI for Total Compensation for All Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(17) All Other: Labor-Related Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code

CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(18) Professional Fees: Nonlabor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(19) Financial Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(20) Telephone Services

We proposed to continue to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(21) All Other: Nonlabor-Related Services

We proposed to continue to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

We received no comments on the proposed price proxies for the operating portion of the 2017-based LTCH market basket and therefore are finalizing the use of these price proxies without modification.

b. Price Proxies for the Capital Portion of the Proposed 2017-Based LTCH Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We proposed to continue to use the same price proxies for the capital-related cost categories as were applied in the 2013-based LTCH market basket, which are provided in Table E7 and described in this section of this rule. Specifically, we proposed to proxy:

- Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).
- Depreciation: Movable Equipment cost category by the PPI Commodity for Machinery and Equipment (BLS series code WPU11).
- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).
- For-profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve).
- Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for LTCH capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We are also proposing to continue to vintage weight the capital price proxies for Depreciation and Interest in order to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2013-based LTCH market basket and is described in section VII.D.4.b.(2). of the preamble of this final rule.

We received no comments on the proposed price proxies for the capital portion of the 2017-based LTCH market basket and therefore are finalizing the use of these price proxies without modification.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2017-based LTCH market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for LTCH capital-related costs. The capital-related component of the proposed 2017-based LTCH market basket reflects the underlying stability of the capital-related acquisition process.

The methodology used to calculate the vintage weights for the proposed 2017-based LTCH market basket is the same as that used for the 2013-based LTCH market basket with the only difference being the inclusion of more recent data. To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the previously mentioned components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, the AHA does provide a consistent database of total expenses back to 1963. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2017. We proposed to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as previously determined. From these annual depreciation amounts we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to LTCHs, we believe this information for all hospitals serves as a reasonable proxy for the pattern of depreciation for LTCHs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2017-based LTCH market basket. We proposed to calculate the expected lives using Medicare cost report data for LTCHs.

The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 18 years, and the average expected life of movable equipment to be equal to 9 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2013-based LTCH-specific market basket, we derived an expected average life of building and fixed equipment of 18 years and an expected average life of movable equipment of 8 years (81 FR 57094).

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. Then we calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as previously provided. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 18 years, and in the case of movable equipment, 9 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2017 back to 1964. These data allow us to derive thirty-seven 18-year periods of capital-related purchases for building and fixed equipment and interest, and forty-six 9-year periods of capital-related purchases for movable equipment. For each 18-year period for building and fixed equipment and interest, or 9-year period for movable equipment, we proposed to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 18-year or 9-year period. This calculation is done for each year in the 18-year or 9-year period and for each of the periods for which we have data. Then we proposed to calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

We received no comments on the proposed methodology to derive the vintage weights for the 2017-based LTCH market basket and therefore are finalizing these vintage weights without modification.

The vintage weights for the capital-related portion of the proposed and final 2017-based LTCH market basket and the 2013-based LTCH market basket are presented in Table E6.

TABLE E6—PROPOSED AND FINAL 2017-BASED LTCH MARKET BASKET AND 2013-BASED LTCH MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year	Building and Fixed Equipment		Movable Equipment		Interest	
	2017-based 18 years	2013-based 18 years	2017-based 9 years	2013-based 8 years	2017-based 18 years	2013-based 18 years
1	0.046	0.044	0.093	0.104	0.031	0.029
2	0.047	0.046	0.096	0.110	0.032	0.031
3	0.046	0.048	0.101	0.117	0.033	0.034
4	0.048	0.050	0.109	0.124	0.036	0.037
5	0.048	0.051	0.113	0.128	0.038	0.039
6	0.051	0.051	0.117	0.132	0.042	0.042
7	0.052	0.051	0.119	0.140	0.045	0.043
8	0.053	0.052	0.124	0.145	0.048	0.046
9	0.055	0.053	0.129	--	0.052	0.049
10	0.057	0.056	--	--	0.056	0.054
11	0.058	0.058	--	--	0.059	0.059
12	0.059	0.059	--	--	0.063	0.063
13	0.061	0.061	--	--	0.068	0.068
14	0.062	0.062	--	--	0.072	0.072
15	0.063	0.062	--	--	0.075	0.076
16	0.063	0.063	--	--	0.078	0.080
17	0.064	0.066	--	--	0.083	0.086
18	0.065	0.067	--	--	0.088	0.091
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table E6 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the FY 2010 IPPS proposed rule.''

c. Summary of Price Proxies of the Proposed 2017-Based LTCH Market Basket

Table E7 shows both the operating and capital price proxies for the proposed and final 2017-based LTCH market basket.

TABLE E7—PRICE PROXIES FOR THE PROPOSED AND FINAL 2017-BASED LTCH MARKET BASKET

Cost Description	Price Proxies
Total	
Compensation	
Wages and Salaries	ECI for Wages and Salaries for All Civilian workers in Hospitals
Employee Benefits	ECI for Total Benefits for All Civilian workers in Hospitals
Utilities	
Electricity	PPI for Commercial Electric Power
Fuel, Oil, and Gasoline	Blend of the PPI for Petroleum Refineries and PPI for Natural Gas
Professional Liability Insurance	
Malpractice	CMS Hospital Professional Liability Insurance Premium Index
All Other Products and Services	
All Other Products	
Pharmaceuticals	PPI Commodity for Pharmaceuticals for human use, prescription
Food: Direct Purchases	PPI for Processed Foods and Feeds
Food: Contract Services	CPI-U for Food Away From Home
Chemicals	Blend of Chemical PPIs
Medical Instruments	Blend of the PPI for Surgical and medical instruments and PPI for Medical and surgical appliances and supplies
Rubber & Plastics	PPI Commodity for Rubber and Plastic Products
Paper and Printing Products	PPI Commodity for Converted Paper and Paperboard Products
Miscellaneous Products	PPI Commodity for Finished Goods Less Food and Energy
All Other Services	
Labor-Related Services	
Professional Fees: Labor-related	ECI for Total compensation for Private industry workers in Professional and related
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support
Installation, Maintenance, and Repair	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair
All Other: Labor-related Services	ECI for Total compensation for Private industry workers in Service occupations
Nonlabor-Related Services	
Professional Fees: Nonlabor-related	ECI for Total compensation for Private industry workers in Professional and related
Financial services	ECI for Total compensation for Private industry workers in Financial activities
Telephone Services	CPI-U for Telephone Services
All Other: Nonlabor-related Services	CPI-U for All Items Less Food and Energy
Capital-Related Costs	
Depreciation	
Building and Fixed Equipment	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (18 years)
Movable Equipment	PPI Commodity for machinery and equipment - vintage weighted (9 years)
Interest Costs	
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (18 years)
For Profit	Average yield on Moody's Aaa bonds - vintage weighted (18 years)
Other Capital-Related Costs	CPI-U for Rent of primary residence

Note: Totals may not sum to 100.0 percent due to rounding

5. FY 2021 Market Basket Update for LTCHs

For FY 2021 (that is, October 1, 2020 through September 30, 2021), we proposed to use an estimate of the proposed 2017-based LTCH market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimated the LTCH market basket update for the LTCH PPS based on IHS Global, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's fourth quarter 2019 forecast with history through the third quarter of 2019, the projected market basket update for FY 2021 is 2.9 percent. Therefore, consistent with our historical practice of estimating market basket updates based on the best available data, we proposed a market basket update of 2.9 percent for FY 2021. Furthermore, because the proposed FY 2021 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.9 percent), we also proposed that if more recent data became subsequently available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2021 annual update in the final rule. (The proposed annual update to the LTCH PPS standard payment rate for FY 2021 is discussed in greater detail in section V.A.2. of the Addendum to the proposed rule.)

Based on the more recent data available for this FY 2021 IPPS/LTCH final rule (that is, IGI's second quarter 2020 forecast of the 2017-based LTCH market basket with historical data through the first quarter of 2020), we estimate that the FY 2021 market basket update is 2.3 percent. We note that the fourth quarter 2019 forecast was developed prior to the economic impacts of the Coronavirus disease 2019 (COVID–19) pandemic. This lower update (2.3 percent) for FY 2021 relative to the proposed rule (3.0 percent) is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets are expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery.

Using the current 2013-based LTCH market basket and IGI's second quarter 2020 forecast for the market basket components, the FY 2021 market basket update would be 2.4 percent (before taking into account any statutory adjustment). Therefore, the update based on the 2017-based LTCH market basket is currently 0.1 percentage point lower. This lower update is primarily due to the lower Pharmaceuticals cost weight in the 2017-based market basket (6.2 percent) compared to the 2013-based LTCH market basket (7.6 percent). This is partially offset by the higher cost weights associated with All Other Services (such as Professional Fees and Installation, Maintenance, and Repair Services) for the 2017-based LTCH market basket relative to the 2013-based LTCH market basket. Table E8 compares the 2017-based LTCH market basket and the 2013-based LTCH market basket percent changes.

TABLE E8—2017-BASED LTCH MARKET BASKET AND 2013-BASED LTCH MARKET BASKET PERCENT CHANGES, FYs 2016 THROUGH 2023

	Fiscal Year (FY)	2017-Based LTCH Market Basket Index Percent Change	2013-Based LTCH Market Basket Index Percent Change
Historical Data	FY 2016	1.8	1.9
	FY 2017	2.4	2.6
	FY 2018	2.4	2.5
	FY 2019	2.3	2.3
	Average 2016-2019	**2.2**	**2.3**
Forecast	FY 2020	2.0	2.0
	FY 2021	2.3	2.4
	FY 2022	2.6	2.7
	FY 2023	2.6	2.7
	Average 2020-2023	**2.4**	**2.5**

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Inc. 2nd quarter 2020 forecast

Over the time period covering FY 2016 through FY 2019, the average growth rate of the 2017-based LTCH market basket is roughly 0.1 percentage point lower than the 2013-based LTCH market basket. The lower growth rate is primarily a result of the lower Pharmaceuticals cost weight in the 2017-based market basket compared to the 2013-based LTCH market basket. Historically, the price growth of pharmaceutical costs has exceeded the price growth rates for most of the other market basket cost categories. Therefore, a lower Pharmaceuticals cost weight would, all else equal, result in a lower market basket update. As previously stated, the Pharmaceuticals cost weights for the 2017-based LTCH market basket and the 2013-based LTCH market basket are based on the 2017 and 2013

Medicare cost report data for LTCHs, respectively.

6. FY 2021 Labor-Related Share

As discussed in section V.B. of the Addendum to this final rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal payment rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. As discussed in more detail in this section of this rule and similar to the 2013-based LTCH market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. As stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42642), the labor-related share for FY 2020 was defined as the sum of the FY 2020 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related Services; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related Costs from the 2013-based LTCH market basket.

We propose to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share and the cost categories in the proposed 2017-based LTCH market basket, we proposed to include in the labor-related share for FY 2021 the sum of the FY 2021 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related cost weight from the proposed 2017-based LTCH market basket.

Similar to the 2013-based LTCH market basket, the proposed 2017-based LTCH market basket includes two cost categories for nonmedical Professional fees (including but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-related and Professional Fees: Nonlabor-related. For the proposed 2017-based LTCH market basket, we proposed to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2013-based LTCH market basket.

As was done for the 2013-based LTCH market basket, we proposed to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and did not receive any public comments in response to the notice (71 FR 8588). A discussion of the composition of the survey and post-stratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

For the proposed 2017-based LTCH market basket, we proposed to apply each of these percentages to the respective 2012 Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the same methodology that we used to separate the 2013-based LTCH market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories.

In the proposed 2017-based LTCH market basket, nonmedical professional fees that were subject to allocation based on these survey results represent approximately 5.6 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we proposed to apportion approximately 3.6 percentage points of the 5.6 percentage point figure into the Professional Fees: Labor-related share cost category and designate the remaining approximately 2.0 percentage points into the Professional Fees: Nonlabor-related cost category.

In addition to the professional services as previously listed, for the 2017-based LTCH market basket, we proposed to allocate a proportion of the Home Office/Related Organization Contract Labor cost weight, calculated using the Medicare cost reports as previously stated, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We proposed to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office and, therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market.

Similar to the 2013-based LTCH market basket, we proposed for the 2017-based LTCH market basket to use the Medicare cost reports for LTCHs to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding their home office provider. Using information on the Medicare cost report, we compared the location of the LTCH with the location of the LTCH's home office. We proposed to classify a LTCH with a home office located in their respective labor market if the LTCH and its home office are located in the same Metropolitan Statistical Area (MSA). Then we determine the proportion of the Home Office/Related Organization Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total Home Office/Related Organization Contract Labor costs for those LTCHs that had home offices located in their respective local labor markets of total Home Office/Related Organization Contract Labor costs for LTCHs with a home office. We determined a LTCH's and its home office's MSA using their zip code information from the Medicare cost report. Using this methodology, we determined that 4 percent of LTCHs' Home Office/Related Organization Contract Labor costs were for home offices located in their respective local labor markets. Therefore, we proposed to allocate 4 percent of the Home Office/Related Organization Contract Labor cost weight (0.1 percentage point = 1.9 percent × 4 percent) to the Professional Fees: Labor-related cost weight and 96 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-related cost weight (1.8 percentage points = 1.9 percent × 96 percent). For

the 2013-based LTCH market basket, we used a similar methodology but we relied on provider counts rather than Home Office/Related Organization Contract Labor costs to determine the labor-related percentage.

In summary, based on the two allocations mentioned earlier, we proposed to apportion 3.7 percentage points of the professional fees and Home Office/Related Organization Contract Labor cost weights into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 0.8 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 4.5 percent.

We received no comments on our proposed methodology to derive the Professional Fees: Labor-Related cost weight and therefore are finalizing this methodology without modification.

As previously stated, we proposed to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related cost weight from the proposed 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2021. Based on IGI's fourth quarter 2019 forecast of the proposed 2017-based LTCH market basket, the sum of the FY 2021 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 63.6 percent. The portion of Capital costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2013-based LTCH market basket. Since the relative importance for Capital is 9.5 percent of the proposed 2017-based LTCH market basket in FY 2021, we took 46 percent of 9.5 percent to determine the proposed labor-related share of Capital for FY 2021 of 4.4 percent. Therefore, we proposed a total labor-related share for FY 2021 of 68.0 percent (the sum of 63.6 percent for the operating cost and 4.4 percent for the labor-related share of Capital).

Based on IGI's second quarter 2020 forecast of the 2017-based LTCH market basket, the sum of the FY 2021 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 63.7 percent. The portion of Capital costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2013-based LTCH market basket. Since the relative importance for Capital is 9.5 percent of the 2017-based LTCH market basket in FY 2021, we took 46 percent of 9.5 percent to determine the labor-related share of Capital for FY 2021 of 4.4 percent. Therefore, using more recent data, the total labor-related share for FY 2021 is 68.1 percent (the sum of 63.7 percent for the operating cost and 4.4 percent for the labor-related share of Capital).

We received several comments on the proposed FY 2021 labor-related share.

Comment: A few commenters opposed the proposed increase to the labor-related share for FY 2021. One commenter stated that the data does not support this increase and that it will result in reduced reimbursements for facilities with an area wage index below 1.0. One commenter requested that CMS reconsider putting this adjustment off for a year to allow LTCHs the opportunity to manage through the challenging COVID pandemic.

Response: We proposed our detailed methodology for deriving the 2017-based LTCH market basket cost weights, which are primarily based on Medicare cost reports submitted by LTCHs. We believe the rebasing and revising of the LTCH market basket is a technical improvement as it reflects a more recent cost structure for LTCHs as well as current price pressures. Likewise, we believe the calculation of the labor-related share should also reflect this technical improvement by being based on more recent data.

After consideration of public comments, we are finalizing a FY 2021 labor-related share of 68.1 percent.

Table E9 shows the FY 2021 labor-related share using the 2017-based LTCH market basket relative importance and the FY 2020 labor-related share using the 2013-based LTCH market basket.

TABLE E9-- FY 2021 LTCH LABOR-RELATED SHARE AND FY 2020 LTCH LABOR-RELATED SHARE

	FY 2021 Final Labor-related Share based on 2017-based LTCH Market Basket[1]	FY 2020 Final Labor-related Share based on 2013-based LTCH Market Basket[2]
Wages and Salaries	47.1	46.6
Employee Benefits	6.8	7.2
Professional Fees: Labor-related[3]	4.4	3.4
Administrative and Facilities Support Services	1.0	0.9
Installation, Maintenance, and Repair Services	2.1	2.1
All Other: Labor-related Services	2.3	2.0
Subtotal	**63.7**	**62.2**
Labor-related portion of capital (46%)	4.4	4.1
Total Labor-Related Share	**68.1**	**66.3**

[1] IHS Global Inc. 2nd quarter 2020 forecast.

[2]Based on IHS Global Inc. 2nd quarter 2019 forecast as published in the August 16, 2019 **Federal Register** (84 FR 42642).

[3]Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office/related organization contract labor costs.

The total difference between the FY 2021 labor-related share using the 2017-based LTCH market basket and the FY 2020 labor-related share using the 2013-based LTCH market basket is 1.8 percentage points (68.1 percent and 66.3 percent, respectively). This difference is attributable to: (1) Revision to the base year cost weights (0.8 percentage point); (2) revision to starting point of calculation of relative importance (base year) from 2013 to 2017 (0.6 percentage point); and (3) using an updated IGI forecast and reflecting an additional year of inflation (0.4 percentage point). The 0.8-percentage point difference in the base year cost weights is primarily due to the incorporation of the 2012 I–O data which shows an increase in the Professional Fees: Labor-Related services.

We note that the use of the Medicare cost report to derive the Home Office/Related Organization Contract Labor cost weight has −0.1 percentage point impact, meaning if we were to use the I–O data to derive the Home Office/Related Organization Contract Labor cost weight, the labor-related share would be 0.1 percentage point higher. The impact of using the Medicare cost report data to calculate the Home Office/Related Organization Contract Labor cost weight is minimal because if we were to instead use the I–O data to derive this weight, it would also increase the residual ''All Other'' cost weight from 28.3 percent (using the Medicare cost report data to calculate the Home Office/Related Organization Contract Labor cost weight) to 30.2 percent (using the I–O data to calculate the Home Office/Related Organization Contract labor cost weight). The higher residual ''All Other'' cost weight then leads to relatively higher cost weight for Administrative and Facilities Support Services which is also reflected in the labor-related share.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section VIII. of the preamble of the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32830 through 32852), we discussed the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program;
- In section VIII.B., the PCHQR Program; and
- In section VIII.C., the LTCH QRP.

In addition, in section VIII.D. of the preamble of that proposed rule (85 FR 32852 through 32858), we proposed changes to the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and critical access hospitals (CAHs).

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

The Hospital IQR Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely-agreed upon quality and cost measures. We have worked with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost

all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509) for the measures we have previously adopted for the Hospital IQR Program measure set for the FY 2022 payment determination and subsequent years. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32830), we did not propose any changes to this policy.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32830), we did not propose any changes to our policies regarding measure removal.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Initiative, our objectives under this framework for quality measurement, and the quality topics that we have identified as high impact measurement areas that are relevant and meaningful to both patients and providers. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32830), we did not propose any changes to these policies.

5. New Measures for the Hospital IQR Program Measure Set

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32830), we did not propose to adopt any new measures.

6. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2022 Payment Determination

This table summarizes the previously finalized Hospital IQR Program Measures for the FY 2022 Payment Determiniation:

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Measures for the FY 2022 Payment Determination		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
COMP-HIP-KNEE *++	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	+
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs)		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS***	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* Finalized for removal from the Hospital IQR Program beginning with the FY 2023 payment determination, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41558 through 41559).

*** In the CY 2019 OPPS/ASC PPS final rule with comment period (83 FR 59140 through 59149), we finalized removal of the Communication About Pain questions from the HCAHPS Survey effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years.

+ Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the inpatient setting.

++ We have updated the short name for the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) measure from Hip/Knee Complications to COMP-HIP-KNEE in order to maintain consistency with the updated Measure ID and hospital reports for the *Hospital Compare* and/or its successor website.

7. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2023 Payment Determination

This table summarizes previously finalized Hospital IQR Program measure set for the FY 2023 Payment Determination:

Measures for the FY 2023 Payment Determination		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	+
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR*	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids***	Safe Use of Opioids – Concurrent Prescribing	3316e

8. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2024 Payment Determination and Subsequent Years

This tables summarizes the previously finalized Hospital IQR Program measure set for the FY 2024 Payment Determination and Subsequent Years

Measures for the FY 2023 Payment Determination		
Short Name	**Measure Name**	**NQF #**
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* In the FY 2020 IPPS/LTCH PPS final rule, we finalized our proposal to remove the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and to replace it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** Finalized in the FY 2020 IPPS/LTCH PPS final rule to add to the eCQM measure subset, beginning with the CY 2021 reporting period/FY 2023 payment determination with a clarification and update (84 FR 42449 through 42459).

+ Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the inpatient setting.

Measures for the FY 2024 Payment Determination and Subsequent Years *		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	+
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR*	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431

Measures for the FY 2024 Payment Determination and Subsequent Years *		
Short Name	**Measure Name**	**NQF #**
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids **	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

** Reporting on the Safe Use of Opioids measure is mandatory for the FY 2024 payment determination.

+ Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the inpatient setting.

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9. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one quarter- of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. In order to successfully participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements.[452] Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the previously discussed description. In accordance with the statute, the FY 2021 payment determination will begin the seventh year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

[452] On March 27, 2020, CMS granted certain reporting requirement exceptions and extensions for subsection (d) hospitals under the Hospital IQR Program. CMS, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' (Mar. 27, 2020) *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*. Submitting such data is therefore not required under the Hospital IQR Program and a hospital that does not submit excepted data will not experience a reduction in APU on that basis.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for

incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We did not propose any changes to these policies.

The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/* (and any other successor CMS-designated websites). The technical specifications used for electronic clinical quality measures (eCQMs) are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). We generally update the measure specifications on an annual basis through the Annual Update, which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. For example, for the CY 2020 reporting period/FY 2022 payment determination, hospitals submitted eCQM data using the May 2019 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*. Hospitals must register and submit quality data through the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). There are safeguards in place in accordance with the HIPAA Privacy and Security Rules to protect patient information submitted through this website. See 45 CFR parts 160 and 164, subparts A, C, and E.

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). We did not propose any changes to these procedural requirements.

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We did not propose any changes to the data submission requirements for chart-abstracted measures.

e. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized reporting and submission requirements for eCQMs, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506). Current reporting and submission requirements were established in the FY 2018 IPPS/LTCH PPS final rule. In that final rule (82 FR 38368 through 38361), we finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41603 through 41604), as well as to the CY 2020 reporting period/FY 2022 payment determination and the CY 2021 reporting period/FY 2023 payment determination in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42503).

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505), we also finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected quarter of data to four quarters of data. We believe that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality measure data for patients and providers. Increasing the number of reported quarters has several benefits. Primarily, a single quarter of data is not enough to capture trends in performance over time. Evaluating multiple quarters of data would provide a more reliable and accurate picture of overall performance. Further, reporting multiple quarters of data would provide hospitals with a more continuous information stream to monitor their levels of performance. Ongoing, timely data analysis can better identify a change in performance that may necessitate investigation and potentially corrective action.

The current policy requiring more limited reporting was established due to stakeholder feedback about challenges in reporting data, and to give hospitals more time to gain experience with reporting (including upgrading systems and training to support eCQM reporting) (82 FR 78355 through 78361). That policy, as well as the changes we proposed, are consistent with our stated goal to create a gradual shift to more robust eCQM reporting (82 FR 38356). Taking an incremental approach over a 3-year period would give hospitals and their vendors time to plan in advance and build upon and utilize investments already made in their EHR infrastructures. We refer readers to section XI.B.7. of the preamble of this final rule for a discussion of the increased collection of information burden associated with this provision. We also refer readers to section VIII.D.6.b of the preamble of this final rule for similar provisions under the Promoting Interoperability Program.

(2) Reporting and Submission Requirements for eCQMs for the CY 2021 Reporting Period/FY 2023 Payment Determination

In the FY 2021 IPPS/LTCH PPS proposed rule, for the CY 2021 reporting period/FY 2023 payment determination, we proposed to increase the amount of data required while keeping the number of eCQMs required the same. Specifically, in the proposed rule, we proposed that hospitals report two self-selected calendar quarters of data for each of the four self-selected eCQMs for the CY 2021 reporting period/FY 2023 payment determination (85 FR 32837).

(3) Reporting and Submission Requirements for eCQMs for the CY 2022 Reporting Period/FY 2024 Payment Determination

In the FY 2021 IPPS/LTCH PPS proposed rule, for the CY 2022 reporting period/FY 2024 payment determination, we proposed to increase the amount of data required while keeping the number and type of eCQMs required the same. Specifically, in the proposed rule, we proposed to require that hospitals report three self-selected calendar quarters of data for the CY 2022 reporting period/FY 2024 payment determination for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM (85 FR 32837).

(4) Reporting and Submission Requirements for eCQMs for the CY 2023 Reporting Period/FY 2025 Payment Determination and Subsequent Years

In the FY 2021 IPPS/LTCH PPS proposed rule, for the CY 2023 reporting period/FY 2025 payment determination and beyond, we proposed to further increase the amount of data required while keeping the number and type of eCQMs required the same. Specifically, in the proposed rule, we proposed to require that hospitals report four calendar quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM (85 FR 32837).

Due to the duplicative nature of comments received on the proposals to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected quarter of data to four quarters of data, we are responding to all comments received on the proposals in section VII.A.9.e.4. of this final rule below.

In addition, the 21st Century Cures Act final rule that appeared in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961) finalized a number of updates to the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). We also refer readers to the CY 2021 Payment Policies Under the Physician Fee Schedule Proposed Rule published August 17, 2020, where we proposed to expand flexibility under the Hospital IQR Program to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria for CEHRT as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608) and for reporting hybrid measures in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 25642 through 25961) and sought public comment on our proposal (85 FR 50271).

Comment: Many commenters supported our proposal to increase the number of quarters for which hospitals are required to report eCQM data. Some commenters specifically appreciated CMS's plan to phase in the requirement over 3 years because they believe a progressive increase will give hospitals and their vendors sufficient time to implement the proposal without being overly burdensome. Other commenters stated the proposal will improve the accuracy and reliability of data, provide a more accurate picture of overall hospital performance, increase hospital accountability, and reduce the likelihood that hospitals will report only their top-performing quarter. Commenters also stated the proposal would enable hospitals and other stakeholders to successfully monitor performance trends, particularly through the CMS *Hospital Compare* site, or successor websites, and enhance patient outcomes.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that we phase in the increased requirements at a faster rate, such as over a 2-year period instead of a 3-year period.

Response: We thank the commenters for their recommendations. We considered a faster implementation timeline in developing our proposal, but ultimately determined to propose to progressively increase the number of required quarters of eCQM data over a 3-year period in order to continue to give hospitals and their vendors time to plan in advance and build upon and utilize investments already made in their EHR infrastructure (85 FR 32837). We believe this approach effectively balances the burdens associated with increased reporting of eCQM data and the benefits of providing that quality data to patients and consumers.

Comment: Many commenters did not support the proposal to require additional quarters of eCQM data in light of the impact of the COVID–19 public health emergency (PHE) on hospitals and requested that eCQM reporting and submission requirements for the CY 2021 reporting period/FY 2023 payment determination remain at one self-selected calendar quarter of data for each of the four self-selected eCQMs. Commenters noted that the COVID–19 PHE has shifted focus away from normal operations, increased burden, and strained hospital resources, particularly impacting staffing and technology. A few commenters indicated that the COVID–19 PHE has limited hospitals' ability to make the IT investments needed to report additional quarters of data. Commenters stated that internal resources have been reallocated or reassigned, that current IT investments are focused on caring for COVID–19 patients via telehealth, and that hospitals are already experiencing burdens or costs associated with implementing additional regulations on information blocking and interoperability. In addition, commenters stated that hospitals are complying with numerous federal and state data reporting requirements related to COVID–19 lab testing, patient volumes, and bed capacity, which are constantly evolving. The commenters stated that, while the duration of the COVID–19 PHE remains uncertain, hospitals expect to be operating in this challenging environment well into CY 2021. Given these challenges, commenters requested that reporting and submission requirements for the CY 2021 reporting period/FY 2023 payment determination remain at one self-selected calendar quarter of data so that hospitals may choose the fourth quarter, providing time for EHR upgrades. A few commenters expressed concern that the proposal could cause hospitals to lose their entire annual payment update (¼ for the IQR, and ¾ for the Promoting Interoperability Program) for failing to meet an eCQM mandate that their EHR vendors cannot deliver due to the pandemic and other competing federal EHR-related mandates. Another commenter stated that the COVID–19 PHE's impact on hospital volumes may render data less reliable. A commenter suggested that CMS continue to monitor the COVID–19 PHE and the extent to which hospitals have recovered to inform the exact timeframe to begin increasing eCQM reporting requirements.

Response: We thank the commenters for their comments and recognize the burden that the COVID–19 PHE has had on the healthcare system. In response to the significant impact of the COVID–19 PHE on hospitals, we issued an array of temporary regulatory waivers and exceptions affecting a wide cross-section of Medicare participation, eligibility, and payment requirements, in an effort to reduce burden, provide flexibility to hospitals, and help hospitals maximize their capacity to

focus on patient care.[453] These waivers and exceptions reduce hospital paperwork burden and reporting requirements, increase flexibility for surge capacity and patient quarantine, allow providers to expand access to telehealth, and enable hospitals to enhance their workforces, among other benefits. In relation to the Hospital IQR Program, we issued a nationwide extraordinary circumstances exception (ECE) that excepted certain data reporting requirements and extended numerous deadlines.[454] Additionally, under the Hospital IQR Program ECE Policy, hospitals may request an exception if they are unable to fulfill program requirements due to extraordinary circumstances not within their control. We refer readers to eCQM ECE resources on QualityNet and 42 CFR 412.140(c)(2) for more information.

As noted previously, our current policy for eCQM reporting requires hospitals to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2020 reporting period/FY 2022 payment determination. Calendar year 2021 will be the fifth year that hospitals have submitted eCQM data, and current reporting and submission requirements were established in the FY 2018 IPPS/LTCH PPS final rule. In that final rule (82 FR 38361), we finalized a policy that eCQM reporting would be required for one self-selected quarter of data for 4 self-selected eCQMs, rather than finalizing our proposal to require reporting on the first three calendar quarters of data for 6 eCQMs in the FY 2018 proposed rule (82 FR 20050 through20051) or continuing our previously finalized policy to require hospitals to submit one full calendar year of data for 8 eCQMs (81 FR 57152). We made this change due to stakeholder concerns about the challenges associated with collecting and reporting eCQM data (82 FR 38355 through 38361). We believed it was important to give stakeholders more time to build and refine their EHR systems and gain experience reporting eCQMs (82 FR 38356). At that time, we stated our intention to gradually transition toward more robust eCQM reporting (82 FR 38356), and we reiterated that intention in a subsequent final rule (84 FR 42502).

As stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32836), we believe that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive quality measure data for patients and providers and that submitting and evaluating multiple quarters of data would provide a more reliable and accurate picture of hospital performance.

Internal review of Hospital IQR Program eCQM submissions data revealed that approximately 97 percent of eligible hospitals successfully submitted one quarter of eCQM data for four self-selected eCQMs for CY 2018 (84 FR 42458). We believe that hospitals have had adequate time to prepare for providing two quarters of data, especially given that hospitals may select to report the third and fourth quarters of CY 2021, allowing them to use the first half of CY 2021 to continue to prepare. After holding eCQM reporting and submission policies constant for a number of years in order to give hospitals and their vendors additional time to improve eCQM reporting capabilities, and stating our intention to transition to more robust reporting, we believe that it is time to increase the level of reporting in order to capture additional quarters of data. As we noted in the proposed rule, we believe that a single quarter of data is not enough to capture trends in performance over time. Our goal in proposing to progressively increase the number of quarters of data to be collected over 3 years was to strike an appropriate balance between increasing eCQM reporting and providing hospitals with the necessary time to implement such changes.

If hospitals are concerned that their annual payment update may be impacted because vendors will be unable to meet the regulatory requirements related to the reporting of electronic clinical quality measures, we emphasize that hospitals may be eligible for an ECE under the IQR program as described above and further below.

Comment: A commenter did not support the proposal to increase the number of self-selected quarters of eCQM data that hospitals must submit for the CY 2021 reporting period/FY 2023 payment determination. The commenter noted that given the unknown future of the impact of the COVID–19 PHE, any increase of eCQM submissions in CY 2021 could have a significant detrimental impact on small, rural hospitals, particularly because many of these hospitals do not find the current eCQMs to be meaningful to their quality improvement. The commenter stated that because mandatory reporting on the Safe Use of Opioid—Concurrent Prescribing eCQM begins in CY 2021, it would be beneficial to evaluate the usefulness and challenges of extracting this data after one quarter rather than requiring two quarters. The commenter also recommended that CMS enhance their eCQM data submission tools so that testing of submission files is available sooner and hospitals can resolve issues prior to the start of the reporting period.

Response: We wish to note to the commenter that, as previously finalized, for the CY 2021 reporting period/FY 2023 payment determination, hospitals will continue to report on four self-selected eCQMs and that reporting on the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM) will not be required until the CY 2022 reporting period/FY 2024 payment determination (84 FR 42503 through 42505). The Safe Use eCQM will be included in the eCQM subset, beginning with the CY 2021 reporting period/FY 2023 payment determination (84 FR 42459) and under our proposal, a hospital may voluntarily select to report on the Safe Use eCQM on two quarters of data at that time.

With respect to the usefulness and challenges of extracting this data after one quarter rather than requiring two quarters, we believe that our proposal further advances our goal of incrementally increasing the use of EHR data for quality measurement and improvement and is responsive to the feedback of some stakeholders urging a faster transition to full electronic reporting (84 FR 42503). In fact, past stakeholder feedback has included the concern that rural hospitals specifically have trouble meeting the minimum reporting threshold when the measurement period is one quarter (84 FR 42502). We also believe that reporting of the Safe Use eCQM will provide valuable information on the area of high-risk prescribing to providers, and further our efforts to combat the negative impacts of the opioid crisis. Further, regarding the challenges of data extraction, the Safe Use eCQM was developed with implementation feasibility and ease in mind. Testing showed that 96 percent of the data elements required to calculate the performance rate are: (1) Collected during routine care; (2) extractable from structured fields in the electronic health systems of test sites; and (3) likely to be accurate. (84 FR 42454).

The meaningfulness of eCQMs to small, rural hospitals, rural health and healthcare remains one of our priorities. In 2016, we established an agency-wide Rural Health Council and in 2017 we launched the Meaningful Measures Initiative and included Improving

[453] See *https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.*

[454] See *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

Access for Rural Communities as an initiative. Additionally, in 2017, we tasked the National Quality Forum (NQF) to establish a Measure Applications Partnership (MAP) Rural Health Workgroup to identify a core set of the best available rural-relevant measures to address the needs of the rural population and provide recommendations from a rural perspective regarding measuring and improving access to care.[455] When selecting eCQMs for inclusion in the measure set we have, and will continue to, consider the recommendations from the rural providers to ensure eCQMs are meaningful to quality improvement for small, rural hospitals.

As for the commenter's recommendation for eCQM submission tool enhancement, we appreciate the commenter's feedback and will take these recommendations into consideration as we assess how to advance eCQM reporting in the Hospital IQR Program. We also note that the eCQM Annual Updates (which include the eCQM specifications, educational materials, value sets, code systems, direct reference codes, terminology, etc.) are released in the spring for the next year's reporting period. For example, the CY 2021 reporting period/FY 2023 payment determination information was released and posted on the eCQI Resource Center in the spring of 2020. This timeframe for updates was adopted in an effort to support EHR system upgrades and development as hospitals and vendors prepare for the next reporting period. We also note that testing becomes available via the HQR System when the submission period opens in the Fall before the Spring eCQM submission deadline.

As to concerns regarding the future of the impact of the COVID–19 PHE, as noted above, we issued a nationwide ECE that excepted certain data reporting requirements and extended numerous deadlines. We will continue to monitor the impact that the COVID–19 PHE has on hospitals, including small, rural hospitals, and will issue additional exceptions as necessary. Additionally, if, due to COVID–19 or any other external circumstance, any hospital—including small, rural hospitals, believes that reporting would have a significant detrimental impact, they can apply for an ECE.

[455] Measures Application Partnership, ''A Core Set of Rural-Relevant Measures and Measuring and Improving Access to Care: 2018 Recommendations from the MAP Rural Health Workgroup'' (Aug. 31, 2018), available at *https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.*

Comment: Many commenters requested that CMS adopt a more incremental approach for increasing the eCQM reporting requirements. A few of the numerous alternative approaches recommended by commenters included postponing the proposed increase in data reporting for one calendar year, postponing the increase until the COVID–19 PHE has abated and hospital volumes return to pre-pandemic levels, and increasing the number of calendar quarters of data to be reported by one quarter every other year.

Response: As noted previously, after delaying increased requirements and setting reduced eCQM requirements for a number of years, we believe that increasing the level of reporting in order to capture additional quarters of data at this time is in line with our goals to gradually increase the robustness of eCQM data (82 FR 38356 and 84 FR 42502). We believe our proposal to progressively increase the number of quarters of eCQM data to be collected over a 3-year period strikes an appropriate balance between increasing eCQM reporting and providing hospitals with the necessary time to implement such changes. We also refer readers to our response above about exceptions during the COVID–19 PHE. We understand the desire to postpone the increased reporting requirements until the pandemic has abated and hospital volumes return to pre-pandemic levels. We note that we proposed requiring hospitals to report only two quarters of data for the CY 2021 reporting period/FY 2023 payment determination. We will continue to monitor the impact that the COVID–19 PHE has on hospitals and will issue additional exceptions as necessary. For calendar year 2021, in the absence of an exception, hospitals will be required to report two quarters of data by the end of the submission period (that is, by the end of February 2022). We note that hospitals may choose to report data from the third and fourth quarters of CY 2021, which may have higher volumes. We will continue to monitor the effects of the PHE on hospitals to ensure our policies remain feasible.

Comment: Several commenters raised concerns about the accuracy, reliability, and validity of eCQM data. A commenter stated the data produced by chart-abstracted measures and eCQMs vary significantly. A few commenters recommended that CMS adopt a more incremental approach to increasing eCQM reporting requirements, or delay its proposal altogether until at least CY 2023, to balance benefits with burdens and better ensure reliability and validity for measurement. A commenter stated it would be premature for CMS to require electronic reporting before all measures are fully electronically specified and field tested. The commenter emphasized the need for providers to have detailed electronic specifications in advance in order to adequately prepare their reporting systems. Another commenter encouraged CMS to evaluate how each additional quarter of data improves accuracy and reliability prior to further increasing the number of required quarters.

Response: We understand the commenters' concern about data reliability and validity and wish to emphasize that all types of quality measures in the Hospital IQR Program, including eCQMs, undergo testing during the measure development process for feasibility, validity, and reliability. We recognize that EHR-based extraction methodology for eCQMs is different from the data collection methodology for chart-abstracted measures, and that measure rates may vary depending on methodology (80 FR 49643–49644). For example, eCQMs utilize data from structured fields within the EHR system, while chart-abstracted measures allow data to be collected from unstructured sources such as a clinician's progress notes. For these reasons, we also use a validation process to address concerns about reliability and validity of eCQM data. As stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32846), we have conducted an eCQM validation pilot (OMB Control #0938–1022) and completed eCQM data validation from the CY 2017 reporting period and the CY 2018 reporting period. Based on our review of the CY 2017 and CY 2018 eCQM data submitted for validation, and on the finding that over half of the measures validated had agreement rates of 80 percent or better, we believe the accuracy of eCQM data is sufficient for continued use of the measures in the Hospital IQR Program and to begin increasing the quarters of data used for the program. As described in section VIII.A.10. of the preamble of this final rule, we are continuously working to improve the eCQM validation process and balance reporting burden. We expect to gain a better understanding of how to increase the accuracy of eCQM data by continuing to analyze that process and the results. Additionally, we believe that the reporting of additional quarters of data by hospitals will help to increase the reliability of the data. We note that eCQM measure specifications for Hospital IQR Program measures can be found on the eCQI

Resource Center,[456] which provides information, tools, and standards for eCQMs. The measure specifications are typically available about eight months prior to the beginning of the calendar year reporting period.

Comment: A few commenters expressed concern about the amount of time that may be required for a hospital or their vendor to internally validate the data and/or create and review CCN files prior to data submission to CMS. A commenter stated the proposal amends more modest, previously finalized policies that hospitals relied on for planning and resource allocation purposes.

Response: We recognize that increasing the number of quarters of eCQM data to be reported can impact a hospital's resource use and refer readers to section XI.B.7 of the preamble of this final rule (information collection requirements) for a detailed discussion of our burden estimates associated with eCQM reporting and submission. We believe the long-term benefits associated with reporting a full year of electronic data will outweigh the burdens and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers. We stated our intention in the FY 2018 IPPS/LTCH PPS final rule to gradually transition toward more robust eCQM reporting (82 FR 38356). We reiterated this stated goal to incrementally increase the use of EHR data for quality measurement in a subsequent final rule (84 FR 42502). We believe that taking an incremental approach to increasing eCQM reporting over a 3-year period will help to ease the burdens associated with reporting larger amounts of data and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting.

Comment: A commenter did not support the proposal because they believed it contradicted the trend to make the program simpler. Another commenter stated there is a high burden on hospitals due to duplications of effort in reporting the same measures in both chart-abstracted and eCQM formats.

Response: We disagree with the commenter that the proposal contradicts our efforts to make the program simpler. Since October of 2017, we have undertaken an ambitious effort to reduce regulatory burden on the healthcare industry, lower health care costs, and enhance patient care by streamlining the quality reporting programs through the Meaningful Measures initiative. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a broader discussion of the Meaningful Measures framework (83 FR 41147). In part due to the adoption of this framework, the number of measures for the Hospital IQR Program has been scaled down significantly, from 65 measures in the FY 2018 payment determination, to 23 measures for the FY 2024 payment determination. We note that the Hospital IQR Program currently includes only two chart-abstracted measures (PC–01-Elective Delivery, NQF #0469, and Sepsis-Severe Sepsis and Septic Shock: Management Bundle, NQF #0500) and that these measures do not overlap with the program's eCQMs. In recent years, we have also improved alignment between Hospital IQR Program's reporting requirements and other quality programs, such as the Promoting Interoperability (PI) program. For example the Hospital IQR Program and Promoting Interoperability Program now have the same eCQMs and data submission requirements. We will continue to look across all quality programs to identify areas for further streamlining and opportunities to reduce any remaining duplication.

Comment: A commenter did not support the proposed expansion of eCQM reporting or public reporting until problems with validation of eCQM data are addressed. The commenter stated that hospitals participating in eCQM data validation continue to report unresolved concerns, such as an inability to authenticate validation results provided for 2017 and 2018 because mismatches on the validation reports were not specifically identified. The commenter stated hospitals and vendors need a better understanding of the cause of mismatches and how to correct them in advance of any public reporting and recommended CMS make improvements to the validation procedures and reports. A few commenters requested that CMS provide additional transparency into the eCQM validation process before increasing the number of quarters required to be reported, such as information on eCQM agreement rates, national eCQM scores, the effect of invalidated data on national and hospital-specific scores, comparisons of the current eCQM data to previously collected chart-abstracted data, and an analysis of how eCQM scores are affected by using the chart-abstracted measure specifications and algorithms for validation. Additionally, the commenters requested that CMS provide analysis of how self-selection of individual eCQMs by each hospital affects the national averages and the number of hospitals reporting each measure.

Response: We appreciate the feedback about hospitals' experience with the eCQM validation process. The specifications for eCQMs contain logic statements and value sets tailored to electronic data sources, and as such, measure specifications and algorithms for chart-abstracted measures are not used for eCQM validation. In other words, we recognize that the information for eCQMs and chart-abstracted measures is pulled from different places and do not use chart-abstracted measure specifications or algorithms for eCQM validation. Based on our review of the CY 2017 and CY 2018 eCQM data submitted for validation, and on the finding that the majority of eCQM data was reported with agreement rates of 80 percent or better, we believe the accuracy of eCQM data is sufficient for continued use of the measures in the Hospital IQR Program and to begin increasing the quarters of data used for the program. We are continuously working to improve eCQM validation and are finalizing several changes to that process in section VIII.A.10 of this final rule. Our decision to extend the educational review process established for chart-abstracted measure validation to eCQM validation may be of particular interest to stakeholders. We also refer commenters to eCQM validation resources on QualityNet.[457] As we make further refinements to eCQM validation policies and practices, we will take the commenters' concerns and suggestions for additional transparency into account. We address concerns related to public reporting of eCQM data in section VIII.A.12.b of the preamble of this final rule.

Comment: A few commenters stated that the required updates to EHRs to modify eCQMs often take significant implementation resources before hospitals are able to report eCQM data. The commenters expressed concern that the proposed increase in data reporting requirements would shorten the timeframe for hospitals to make and validate required measure logic changes, which would require hospitals to expend additional resources in order to finish changes on time. The commenters

[456] The eCQI Resource Center is available at: *https://ecqi.healthit.gov/.*

[457] eCQM Data Validation Resources are available on QualityNet at: *https://www.qualitynet.org/search?q=validation.*

requested that CMS provide hospitals with 18 months to implement changes.

Response: We disagree that there is not enough time to implement changes in eCQM data reporting requirements for existing eCQMs, which are related to, but separate from, adding new eCQMs in EHRs. We note that the eCQM specifications are typically available about eight months prior to the beginning of the calendar year reporting period. Once the eCQM updates are implemented in hospital EHRs, reporting an additional quarter of data should not require the same level of effort as reporting one initial quarter of data because hospitals should not need to update the eCQM specifications each quarter. Thus, we do not expect hospitals to experience a significant amount of added burden reporting three additional quarters of data over a 3-year period. We do thank the commenters for their feedback and will take this information into account when modifying the eCQM measure set in future rulemaking. We note that we did not propose to modify, remove, or add any eCQM measures to the Hospital IQR Program in the FY 2021 IPPS/LTCH PPS proposed rule. However as noted above, in the CY 2021 Payment Policies Under the Physician Fee Schedule Proposed Rule published August 17, 2020, we are proposing to update CEHRT requirements to allow for additional flexibility (85 FR 50271). We believe this flexibility should be helpful to hospitals as they navigate the timing of the changes, because hospitals would be able use either: (1) Technology certified to the 2015 Edition criteria for CEHRT as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537–41608) and for reporting hybrid measures in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 25642 through 25961).

Comment: A few commenters expressed concern about variation in readiness and eCQM reporting capabilities across hospitals. Commenters recommended that CMS work with stakeholders to identify underlying structural problems and barriers to successful reporting; consider a process by which hospitals could request and receive a one-year extension, if needed, to increase their eCQM reporting to four calendar quarters; or take a more incremental approach to increasing eCQM reporting requirements.

Response: As stated previously, we reduced or delayed eCQM reporting requirements for a number of years, as compared to reporting requirements for other Hospital IQR Program measures, to give hospitals and their vendors additional time to upgrade IT systems, improve data mapping and other capabilities, and increase staff training for eCQM reporting. In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to progressively increase the number of quarters of data to be collected over three years to continue to give providers time to gain experience with eCQM reporting and submission. We believe that gradually increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality measure data for patients and providers, and we believe it is time for such an increase. We also refer stakeholders to a discussion about our ECE policies in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49695, 49713) as well as eCQM ECE resources on QualityNet. These resources discuss changes to the Hospital IQR Program ECE policy to provide flexibility for hospitals undergoing extraordinary hardships related to reporting eCQM data. While we are able to grant exceptions via our ECE policy, we note that granting an extension for eCQM reporting under an ECE policy is not operationally feasible. We will continue to work with stakeholders to identify any structural issues or barriers to successful reporting.

Comment: Several commenters requested clarification about the data submission process associated with increasing the number of quarters of data required to be reported. Specifically, commenters asked CMS to clarify the timing of submission deadlines and the ability of hospitals to report non-consecutive quarters of data. A commenter requested that CMS clarify that until all four quarters of data are required, the hospital will be able to self-select which quarters it reports on.

Response: In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Promoting Interoperability Program—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We did not propose any changes to the Hospital IQR Program eCQM submission deadlines in the FY 2021 IPPS/LTCH PPS proposed rule. We note that in this final rule, the Promoting Interoperability Program is finalizing a proposal that the submission period for the Promoting Interoperability Program would continue to be the 2 months following the close of the respective calendar year (85 FR 32857). Thus, the data submission deadline for eCQM data under the Hospital IQR Program, regardless of how many quarters of data are required to be reported for a given calendar year, will continue to be the end of 2 months following the close of the respective calendar year. In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to require that hospitals report two self-selected calendar quarters of data for each of the four self-selected eCQMs for the CY 2021 reporting period/FY 2023 payment determination and that hospitals report three self-selected calendar quarters of data for the CY 2022 reporting period/FY 2024 payment determination for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM (85 FR 32837). Thus hospitals would self-select the quarters it reported on until all four quarters were required. The ability self-select quarters would permit hospitals to submit non-consecutive quarters of data.

Comment: Two commenters stated that changing IT systems in a given year, or partnering with new entities with different medical record systems to coordinate care, could make eCQM data submission challenging for hospitals. They asked CMS to provide flexibility and guidance for those hospitals. Another commenter asked if hospitals would be required to submit numerator and denominator data, noting that a requirement to submit combined files would be a major issue for any hospital that converts to a different electronic health record (EHR) system.

Response: We refer readers to the FY 2016 IPPS/LTCH PPS final rule, in which we indicated that hospitals may also use abstraction or may pull the data from non-certified sources and then input these data into CEHRT to capture and report QRDA I files (80 FR 49706). The ability to abstract or pull data from non-certified sources to then input this data into CEHRT reinforces the importance of ensuring the system is properly mapped for consistent and correctly captured data for accurate program reporting. We also expanded the ECE policy to include requests related to the submission of eCQM data if a hospital experiences a hardship that prevents it from eCQM reporting. Specifically, in the FY 2016 IPPS/LTCH PPS final rule, we finalized a policy, effective starting with the FY 2018 payment determination, to allow hospitals to utilize the existing ECE form (OMB control number 0938–1022 (expiration date December 31, 2022)) to request an exception to the Hospital IQR Program's eCQM reporting requirement

for the applicable program year based on hardships preventing hospitals from electronically reporting (80 FR 49695, 49713). We stated that such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification (80 FR 49695, 49713)). We assess a hospital's request on an individual basis to determine if an exception is merited (80 FR 49695, 49713). We also refer stakeholders to additional eCQM ECE resources on QualityNet.[458]

Comment: A commenter requested clarification on alignment of the timeline for eCQM reporting and submission and the timeline for the transition from the Quality Data Model (QDM) common data layout (CDL) to QI Core FHIR clinical quality language (CQL) based specifications for eCQMs. The commenter stated their belief that the proposal to increase the data reporting period was intended to facilitate the transition to QI Core FHIR CQL specifications in 2022 to 2024 and noted that an underlying change in standards for certified EHR technology and the potential impact on workflows would require a slower transition. The commenter recommends that CMS transition to four quarters of reporting in CY 2021 if the transition to QI CORE FHIR CQL will take place after 2024, because the eCQMs available for the program are established, eligible hospitals should be able to capture the data with little additional burden, and a full year of data is more meaningful.

Response: In the FY 2020 IPPS/LTCH PPS final rule, we explained that we were investigating and testing the potential uses of the FHIR standard [459] for EHR-based quality measure data reporting, but noted it was not required at the time. (84 FR 42471). We do not have a defined timeline for new eCQMs that would be written using QI-Core as the data model. We interpret the comment to mean that the commenter believes a transition to the QI Core FHIR CQL in the 2022 to 2024 timeframe would necessitate a slower transition to the requirement to report a full year of eCQM data. We will take this concern into consideration as we continue to evaluate a transition to the QI Core FHIR CQL and note that any modifications to eCQMs would be made through notice and comment rulemaking per our policies to provide an opportunity for public comment on the proposal. In the meantime, we refer stakeholders to the QI Core Implementation Guide for more information on QDM to QI Core R4 Draft Mapping.[460]

Comment: Several commenters expressed concerns about the eCQM data submission process and described challenges in reporting eCQM data through the QualityNet Secure Portal. Commenters stated that the CMS system regularly experiences technical difficulties with a single quarter of data and expressed concern that submission of larger files will strain the system, resulting in multiple submission attempts by hospitals and further increasing burden. A commenter stated that some hospitals that voluntary reported in 2019 found their data to be incomplete and had to institute changes to ensure complete and timely claims data. Another commenter noted the inability of the QualityNet Secure Portal to receive test submissions until the second half of each calendar year, and expressed concern that hospitals will not be able to test, correct, and submit their Q1 or Q2 data until sometime in Q3 or Q4 (or later). Commenters urged CMS to improve the capacity of the QualityNet Secure Portal, including improving the capacity to receive test and production QRDA I files and send submission summary and performance reports, before considering additional eCQM data reporting requirements.

Response: We thank the commenters for their feedback. The legacy Hospital Quality Reporting (HQR) System began transitioning to the Next Generation of the HQR System for eCQM reporting with the CY 2019 reporting period to improve the experience for program stakeholders. We will continue to make changes to improve the system's usability. The feedback generated by the HQR System improves data quality and supports a submitter's efforts to achieve successful data submission. We note that we continue to improve the eCQM reporting process. Recent improvements include a new HQR System Home Page, refined eCQM user interfaces (UI), and an updated HQR quality data file submission platform. An export of episode of care measure outcomes is now available for users within 24 hours of submission, which allows users to sort and filter data, improving the overall reporting process and driving data quality by providing timely, confidential feedback.[461]

Comment: A few commenters asked CMS to clarify the number of files required, whether eCQMs should be reported as separate reports, and if CMS would provide clear instructions to help hospitals develop and submit large data files.

Response: We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) for our previously adopted eCQM file format specifications, which require that hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format; (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from noncertified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. We have also clarified that hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387). More specifically regarding the use of QRDA I files, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170), we stated that we expect QRDA I files to reflect data for one patient per file per quarter.

In order to fulfill these requirements, hospitals are expected to report QRDA I, patient-level files representative of their patient population for the specified reporting quarter. With regard to the comment on the submission of larger QRDA I files, the maximum QRDA I patient file size remains 10MB. We are maintaining our established submission format of one patient, per file, per quarter, which includes all patient encounters, eCQMs and applicable data elements for those measures. Maintaining this process is intended to reduce provider burden through the preservation of established file requirements so that submitters are familiar and experienced with eCQM reporting.

In addition, users are able to submit multiple quarters of patient data within one batch file to the HQR System, with

[458] See *https://www.qualitynet.org/inpatient/measures/ecqm/participation#tab2.*

[459] FHIR, developed by Health Level Seven International (HL7), is designed to enable information exchange to support the provision of healthcare in a wide variety of settings. The specification builds on and adapts modern, widely used RESTful practices to enable the provision of integrated healthcare across a wide range of teams and organizations. Additional information is available at: *https://www.hl7.org/fhir/overview.html.*

[460] The current version of the implementation guide may be found at: *http://hl7.org/fhir/us/qicore/qdm-to-qicore.html.*

[461] A Comma Separated Values (CSV) file allows data to be exported and saved in a spreadsheet format for easy viewing and use of the data.

a maximum of 14,999 QRDA I files in a batch. Hospitals are encouraged to submit the volume of batches needed to fully represent their patient population for the specified reporting quarter. The HQR System will break down the information that identifies which quarter of data is being submitted. When the submitters generate the reports within the HQR System, they will see the data for the specified quarter.

Comment: A few commenters requested additional clarity regarding the acceptable level of structural data errors in eCQM files. The commenters stated some errors cannot be retroactively resolved, which could impact hospitals' ability to successfully report all quarters if a certain threshold of error is not accepted.

Response: We thank the commenters for this feedback. The QRDA I file format is the required format to submit eCQM data for the Hospital IQR and Promoting Interoperability Programs (80 FR 49706; 80 FR 49759 through 49760). A number of resources, such as the Implementation Checklist eCQM Annual Update, CMS Implementation Guide and sample files, and eCQM Data Element Repository (provides clarification, definitions and clinical focus for all eCQM data elements) are available on the eCQI Resource Center to aid data submitters and their Health IT Vendors to prevent structural data errors.[462] We encourage submitters to test early and often to prevent or reduce the likelihood of structural errors in production data that would generate conformance statements clarifying why the patient file is being rejected. Hospitals are expected to continue working with their health IT vendor to resolve any structural data issues and resubmit the QRDA I files to achieve successful submission.

Comment: A few commenters recommended that CMS monitor implementation of the proposal, such as soliciting feedback from hospitals to learn about reporting challenges and to ensure that the proposal does not impose substantial additional administrative burdens during the COVID–19 PHE. A commenter recommended that CMS work with stakeholders to ensure eCQM data provides actionable insights that support performance improvement, considering the burden required to report it.

Response: We thank the commenters for their suggestions. We plan to monitor the implementation of the increased reporting requirements for eCQM data and welcome continued feedback from stakeholders through webinars, listservs, and help desk questions.

Comment: A commenter expressed concern about reporting fourth quarter data due to complexities caused by changes in ICD–10 codes, measures specifications, and value sets. The commenter indicated that resolving these issues constrains hospitals to two quarters of workable data. Another commenter stated that reporting data on all four calendar quarters would be problematic because vendor updates incorporating eCQM specification changes into EHR systems generally do not occur until mid-year, with the deadline for eCQM reporting for a year occurring during the first calendar quarter of the subsequent year. The commenter believes that to avoid confusion, vendor updates to the eCQM specifications should not take place prior to that data submission.

Response: The eCQM Annual Updates (which include the eCQM specifications, educational materials, value sets, code systems, direct reference codes, terminology, etc.) are typically released in the spring for the subsequent year's reporting period. For example, we posted this information on the eCQI Resource Center in the spring of 2020 applicable for the CY 2021 reporting period/FY 2023 payment determination. We have used this timeframe in an effort to support EHR system upgrades and development as hospitals and vendors prepare for the next reporting period. Any updates to the value sets, code systems (including ICD–10 codes), implementation guides, or other materials can be found on the eCQI Resource Center, which functions as the one-stop shop for the most current information to support electronic clinical quality improvement. Historically, hospitals have voluntarily submitted or been required to report on at least one quarter of eCQM data by the identified submission deadline. Since mandatory eCQM reporting for the Hospital IQR Program began with the CY 2016 reporting period [80 FR 49693 through 49698], a growing number of hospitals have voluntarily and successfully reported two or more quarters of data prior to the submission period deadline, including the fourth quarter of data.

After consideration of comments received, we are finalizing our proposal as proposed to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected quarter of data to four quarters of data. Specifically, for the CY 2021 reporting period/FY 2023 payment determination, hospitals will be required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs. For the CY 2022 reporting period/FY 2024 payment determination, hospitals will be required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals will be required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQMs. In addition, we are clarifying that until hospitals are required to report all four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination, they may submit either consecutive or non-consecutive self-selected quarters of data. We also refer readers to section VIII.D. of this final rule where we are also finalizing similar polices under the PI Program.

(3) Continuation of Certification Requirements for eCQM Reporting

(a) Requiring Use of 2015 Edition Certification Criteria

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41604 through 41607), to align the Hospital IQR Program with the Promoting Interoperability Program, we finalized a policy to require hospitals to use the 2015 Edition certification criteria for certified EHR technology (CEHRT) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years. While we did not propose any changes to this policy in the FY 2021 IPPS/LTCH PPS proposed rule, as stated above, we did propose changes to this policy in the CY 2021 Payment Policies Under the Physician Fee Schedule Proposed Rule published August 17, 2020. To reiterate, the 21st Century Cures Act final rule that appeared in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961) finalized a number of updates to the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). In general, health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers. In the CY 2021 Payment Policies Under the Physician Fee Schedule Proposed Rule published August 17, 2020, specifically, we proposed to expand flexibility under the Hospital IQR Program to allow hospitals to use either: (1) Technology certified to

[462] See the eCQI Resource Center at: *https://ecqi.healthit.gov/.*

the 2015 Edition criteria for CEHRT as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537–41608) and for reporting hybrid measures in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 25642 through 25961) and sought public comment on our proposal (85 FR 50271).

(b) Requiring EHR Technology To Be Certified to All Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We did not propose any changes to this policy in the FY 2021 IPPS/LTCH PPS proposed rule. However, as mentioned above, we refer readers to the CY 2021 Payment Policies Under the Physician Fee Schedule Proposed Rule published August 17, 2020, where we proposed to expand flexibility under the Hospital IQR Program to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria for CEHRT as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537–41608) and for reporting hybrid measures in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 25642 through 25961) and sought public comment on our proposal (85 FR 50271).

(4) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format as was previously required; (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170), we stated that we expect QRDA I files to reflect data for one patient per file per quarter, and that they contain the following four key elements that are utilized to identify the file:

- CMS Certification Number (CCN).
- CMS Program Name.
- EHR Patient ID.
- Reporting period specified in the Reporting Parameters Section per the CMS Implementation Guide for the applicable reporting year, which is published on the eCQI Resource Center website at *https://ecqi.healthit.gov/QRDA*.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to add EHR Submitter ID to the four key elements listed, as previously discussed, as a fifth key element for file identification beginning with the CY 2021 reporting period/FY 2023 payment determination (85 FR 32837). An EHR Submitter ID is the ID that is assigned by QualityNet to submitter entities upon registering into the system and will be used to upload QRDA I files. For vendors, the EHR Submitter ID is the Vendor ID; for hospitals, the EHR, Submitter ID is the hospital's CCN. Particularly for situations when a hospital uses one or more vendors to submit QRDA I files via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System), this additional element would prevent the risk of a previously submitted file by a different vendor unintentionally being overwritten. Therefore, hospitals would be required to submit the following elements to identify the QRDA 1 file:

- CMS Certification Number (CCN).
- CMS Program Name.
- EHR Patient ID.
- Reporting period specified in the Reporting Parameters Section.
- EHR Submitter ID.

Comment: A few commenters supported our proposal to add EHR Submitter ID to the four key elements listed as a fifth key element for file identification. A commenter asked CMS to adopt a standard to keep the QRDA file formats and quality metrics consistent for the duration of the 3 year reporting period, stating that it can take 6–10 months to implement file format or metrics changes, which may lead to data inconsistencies.

Response: We thank the commenters for their support. We will take the request related to the consistency of the QRDA file formats and quality metrics into consideration for future rulemaking.

After consideration of the public comments received, we are finalizing our proposal as proposed to add EHR Submitter ID as the fifth key element for file identification beginning with the CY 2021 reporting period/FY 2023 payment determination.

(5) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR and Medicare Promoting Interoperability Programs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program—the end of 2 months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline may be moved to the next business day if it falls on a weekend or federal holiday. In the FY 2021 IPPS/LTCH PPS proposed rule, we did not propose any changes to the eCQM submission deadlines. Even though hospitals will be required to gradually increase the number of quarters of eCQM data submitted, the submission deadline does not change. Hospitals must still submit eCQM data by the end of the data submission time period regardless of how many quarters of data are required to be reported for a given calendar year. That time period will continue to be the 2 months following the close of the respective calendar year. For example, for the CY 2021 reporting period/FY 2023 payment determination, hospitals should submit data by Monday, February 28, 2022.

f. Data Submission and Reporting Requirements for Hybrid Measures

(1) Background

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid Hospital-Wide Readmission (HWR) measure for the CY 2018 reporting period. For data submission and reporting requirements under the 2018 Voluntary Reporting Period, we finalized that the 13 core clinical data elements and six linking variables for

the Hybrid HWR measure be submitted using the QRDA I file format, and that hospitals voluntarily reporting data for the Hybrid HWR measure could use EHR technology certified to the 2014 Edition, the 2015 Edition, or a combination thereof (82 FR 38394 through 38397). In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) as well as a number of requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508). We adopted the Hybrid HWR measure into the Hospital IQR Program in a stepwise fashion, first accepting data submissions for the Hybrid HWR measure during two voluntary reporting periods (84 FR 42479). Beginning with the FY 2026 payment determination, hospitals are required to report on this measure (84 FR 42479).

(2) Certification and File Format Requirements

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), we finalized a requirement that hospitals use EHR technology certified to the 2015 Edition to submit data on the Hybrid HWR measure. In addition, we finalized that the core clinical data elements and linking variables identified in hybrid measure specifications must be submitted using the QRDA I file format. In order to ensure that the data have been appropriately connected to the encounter, the core clinical data elements specified for risk adjustment need to be captured in relation to the start of an inpatient encounter. The QRDA I file standard enables the creation of an individual patient-level quality report that contains quality data for one patient for one or more quality measures.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to continue the policy that requires hospitals to use EHR technology certified to the 2015 Edition to submit data on the Hybrid HWR measure and expand this requirement to apply to any future hybrid measure adopted into the Hospital IQR Program's measure set (85 FR 32838). We also clarified that core clinical data elements and linking variables must be submitted using the QRDA I file format for future hybrid measures in the program. We invited public comment on our proposals.

As discussed above, the 21st Century Cures Act final rule finalized a number of updates to the 2015 Edition of health IT certification criteria. Since publication of the FY 2021 IPPS/LTCH PPS proposed rule, we proposed in the CY 2021 PFS proposed rule to allow hospitals to continue to use technology certified to the 2015 Edition criteria for CEHRT or to use technology certified to the 2015 Edition Cures Update standards (85 FR 50271). If finalized, this would mean that hospitals could continue to use their current edition or update to the updated edition when made available by their vendor.

Comment: A few commenters supported the proposal but asked CMS to monitor the experience of voluntarily reporting the Hybrid Hospital-Wide Readmission measure and make amendments in future rulemaking, as necessary. Those commenters noted hospitals' limited experience with reporting the hybrid readmission measure and stated that electronic health record vendors are still building out the functionality for reporting.

Response: We thank the commenters for their support and will continue to monitor the experience of reporting the hybrid measure to determine if modifications in future rulemaking are necessary.

Comment: A commenter requested clarification regarding whether the proposal requires a specific functionality in CEHRT or certification criteria in order to be compliant with the hybrid measure reporting requirements or if the proposal is a general requirement for the hospital to have CEHRT capable of reporting eCQMs.

Response: Our proposal in the FY 2021 IPPS/LTCH PPS proposed rule requires hospitals to use EHR technology certified to the 2015 Edition to submit data on the Hybrid Hospital-Wide Readmission measure and any future hybrid measures adopted into the Hospital IQR Program measure set. However as mentioned above, since publication of that rule, we have made another proposal expanding flexibilities to allow hospitals to use either the 2015 Edition or the 2015 Edition Cures Update in the CY 2021 PFS proposed rule (85 FR 50271) and refer readers to that rule for additional detail. If finalized, this would mean that hospitals could use either: (1) Technology certified to the 2015 Edition criteria for CEHRT as was previously finalized for reporting hybrid measures (84 FR 42507), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule.

Comment: A commenter expressed concern about the addition of any new hybrid measures until hospitals have recovered from the COVID–19 PHE and urged CMS to limit the number of hybrid measures introduced within the program in years where it increases the number of calendar quarters required for reporting.

Response: We did not propose any additional measures in the FY 2021 IPPS/LTCH PPS proposed rule, but will take the commenter's concerns into consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals as proposed to continue the policy that requires hospitals to use EHR technology certified to the 2015 Edition to submit data on the Hybrid HWR measure and expand this requirement to apply to any future hybrid measure adopted into the Hospital IQR Program's measure set. However, as noted above, we refer readers to our proposal in the CY 2021 PFS proposed rule to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria for CEHRT for reporting eCQMs and hybrid measures or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 50271).

(3) Additional Submission Requirements

In the FY 2020 IPPS/LTCH PPS final rule, we finalized allowing hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and/or case threshold exemptions (84 FR 42507). We also finalized applying similar zero denominator declaration and case threshold exemption policies to hybrid measure reporting as we allow for eCQM reporting (84 FR 42507 through 42508). We did not propose any changes to the hybrid measure reporting and submission requirement supporting any combination of data via QRDA I files, zero denominator declaration, and/or case threshold exemptions. We note that the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at § 170.315(c)(3) to refer to CMS QRDA Implementation Guides and removes the Health Level 7 (HL7®) QRDA standard requirements (85 FR 25645). Based on our data, the majority of Hospital IQR Program participants already use the CMS QRDA I Implementation Guide for Hospital Quality Reporting for submission of eCQMs to the Hospital IQR Program. Under our proposal in the CY 2021 PFS proposed rule, discussed above, hospitals would have the flexibility to use either: (1) Technology certified to the 2015 Edition criteria for CEHRT for reporting eCQMs and hybrid measures, or (2) technology certified to the 2015

Edition Cures Update standards as finalized in the 21st Century Cures Act final rule (85 FR 50271). As with eCQM reporting, we encourage all hospitals and their health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as submitting test files to the Hospital Quality Reporting (HQR) System, to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline.[463]

(4) Submission Deadlines for Hybrid Measures

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42508), where we finalized submission deadlines for hybrid measures. We did not propose any changes to these policies.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We did not propose any changes to this policy.

h. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at: *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We did not propose any changes to these policies in this final rule.

[463] We recently decommissioned the Pre-Submission Validation Application (PSVA) tool within the HQR System because the system itself now performs the same functions that the PSVA tool previously did.

i. Data Submission Requirements for Structural Measures

There are no remaining structural measures in the Hospital IQR Program.

j. Data Submission and Reporting Requirements for CDC NHSN HAI Measures

For details on the data submission and reporting requirements for Healthcare-Associated Infection (HAI) measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553), in which we finalized the removal of five of these measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) from the Hospital IQR Program. As a result, hospitals will not be required to submit any data for those measures under the Hospital IQR Program following their removal beginning with the CY 2020 reporting period/FY 2022 payment determination. However, the five CDC NHSN HAI measures are included in the HAC Reduction and Hospital VBP Programs and reported via the CDC NHSN portal (83 FR 41474 through 41477; 83 FR 41449 through 41452). We further note that the HCP measure remains in the Hospital IQR Program and will continue to be reported via NHSN. We did not propose any changes to these policies.

10. Validation of Hospital IQR Program Data

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 through 41608) for detailed information on validation processes for chart-abstracted measures and eCQMs, and previous updates to these processes for the Hospital IQR Program.

Validation for chart-abstracted measures has been updated over recent years as the number of chart-abstracted measures has been reduced. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41562 through 41567), we removed four clinical process of care measures,[464] and noted that for the CY 2021 reporting period/FY 2023 payment determination and subsequent years, only one clinical process of care measure (SEP–1) remains in the program for chart-abstracted validation (83 FR 41608).

We adopted the process for validating eCQM data in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181). Validation of eCQM data was finalized for the FY 2020 payment determination and subsequent years (starting with the validation of CY 2017 eCQM data that would impact FY 2020 payment determinations). We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), in which we finalized several updates to the processes and procedures for validation of CY 2017 eCQM data for the FY 2020 payment determination, validation of CY 2018 eCQM data for the FY 2021 payment determination, and eCQM data validation for subsequent years.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to incrementally combine the validation processes for chart-abstracted measure data and eCQM data and related policies in a stepwise process (85 FR 32839). To accomplish this, we proposed to: (1) Update the quarters of data required for validation for both chart-abstracted measures and eCQMs; (2) expand targeting criteria to include hospital selection for eCQMs; (3) change the validation pool from 800 hospitals to 400 hospitals; (4) remove the current exclusions for eCQM validation selection, (5) require electronic file submissions for chart-abstracted measure data; (6) align the eCQM and chart-abstracted measure scoring processes; and (7) update the educational review process to address eCQM validation results. We believe these proposals would ultimately streamline the validation process and reduce the total number of hospitals selected for validation. These are discussed in detail in the following sections.

[464] In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41562 through 41567), we removed three clinical process-of-care measures (IMM–2, ED–1, and VTE–6) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years, and one clinical process of care measure (ED–2) for the CY 2020 reporting period/FY 2022 payment determination and subsequent years.

b. Submission Quarters

(1) Current Policy

Currently, we require hospitals selected for chart-abstracted measures to submit data from the Q3 and Q4 of the calendar year, 3 years before the payment determination and the Q1 and Q2 of the calendar year, 2 years before the payment determination (FY 2014 IPPS/LTCH final rule (78 FR 50822 through 50823). This is because there is a lag associated with validation. In general, validation is a year behind. Validation results affecting a certain FY payment determination are based on measures submitted for the prior payment determination. For example, validation results affecting the FY 2024 payment determination are based on measures submitted for the FY 2023 payment determination (CY 2021 discharge period with data submission completing in CY 2022).

For validation affecting the FY 2023 payment determination, hospitals must submit data to validate chart-abstracted measures from the Q3 and Q4 of CY 2020 and the Q1 and Q2 of CY 2021. These are data originally submitted for the FY 2022 program payment determination. Depending on whether a hospital is selected as a random or targeted hospital, CMS requests data between 1 and 5 months following the data reporting submission deadline for a given reporting quarter. Following this request, hospitals have 30 days to submit randomly selected medical records to the Clinical Data Abstraction Center (CDAC), and after submission, CMS validates the data in preparation to make the associated payment determination. Under the current policy, hospitals selected for eCQM validation for a given payment determination year are required to provide medical records for a sample of cases occurring during one of the self-selected calendar quarters of the year 3 years before that payment determination (82 FR 38399 through 38400). For example, for validation affecting the FY 2023 payment determination period, hospitals selected during CY 2021 for eCQM validation are required to submit data from one self-selected quarter out of the 4 calendar quarters of 2020, that is Q1 through Q4 of CY 2020 (82 FR 38398 through 38403). These requirements are illustrated in the following table.

Current Quarters Required for Validation Affecting FY 2023 Payment Determination		
Measures Submitted	**Required Quarters of Data for Validation**	**Validation Data Request Timeframe**
Chart-Abstracted Measures	3Q 2020	4Q 2020 – 1Q 2021
	4Q 2020	1Q – 2Q 2021
	1Q 2021	2Q-3Q 2021
	2Q 2021	3Q -4Q 2021
eCQMs	1Q 2020 - 4Q 2020	2Q – 3Q 2021

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, we proposed to shift the quarters of data used for both chart-abstracted measure validation and eCQM validation in an incremental manner in order to align the two over time.

(2) Quarters Required for Validation Affecting the FY 2023 Payment Determination

In order to align the quarters of data used for chart-abstracted measure validation and eCQM validation, we proposed to first change the period for validation affecting the FY 2023 payment determination. Instead of validating chart-abstracted measure data from Q3 2020–Q2 2021, we proposed to validate measure data only from the Q3 and Q4 of CY 2020 for validation affecting the FY 2023 payment determination for chart-abstracted measures (illustrated in Table: 2 that follows) as a transition year. Specifically, this means that we would not require facilities to submit data for chart-abstracted measure validation for the Q1 and Q2 of CY 2021 for validation affecting the FY 2023 payment determination. We would use measure data from only two quarters (Q3 and Q4 of CY 2020) for hospitals selected under both the random and targeted chart-abstracted measure validation. We note that this proposal only affects chart-abstracted measure validation; we would continue to validate the self-selected quarter of eCQM data submitted during 2020 for validation affecting the FY 2023 payment determination as previously finalized.

Updates to Quarters Required for Validation Affecting the FY 2023 Payment Determination	
Measures Submitted	Required Quarters of Data for Validation
Chart-Abstracted Measures	3Q 2020
	4Q 2020
eCQMs	1Q 2020 - 4Q 2020

Comment: Several commenters supported using Q3 and Q4 2020 data for validation affecting the FY 2023 payment determination.

Response: We thank these commenters for their support.

Comment: A commenter recommended that CMS not increase the number of quarters required for validation at this time because many hospitals are responding to the COVID–19 PHE, and therefore, may not have sufficient resources to submit this data.

Response: We acknowledge that many hospitals may be affected by the COVID–19 PHE. However, we note that for validation affecting the FY 2023 payment determination (that is, the first payment determination affected by these changes), we are only requiring submission of chart-abstracted measure validation for two quarters (specifically, Q3 and Q4 of CY 2020), which represents a reduction in the number of quarters that hospitals were previously required to submit; the previous requirement was four quarters. We note that there are no changes to the number of quarters of CY 2020 data required to be submitted for eCQM validation

affecting FY 2023 payment determination. Furthermore, we have granted an exception to medical record submission requirements for eCQM validation for CY 2019 discharges (submission would have been required in 2020) because of the COVID–19 PHE [465] which we believe further reduces validation related burden.

After consideration of the public comments we received, we are finalizing our proposal as proposed to validate measure data only from the Q3 and Q4 of CY 2020 for validation affecting the FY 2023 payment determination for chart-abstracted measures as a transition year.

(3) Quarters Required for Validation Affecting the FY 2024 Payment Determination and Subsequent Years

For validation affecting the FY 2024 payment determination and subsequent years, we proposed to use Q1–Q4 data of the applicable calendar year for validation of both chart-abstracted measures and eCQMs. For example, the quarters required for validation affecting the FY 2024 payment determination would occur as displayed in the following table.

Example: Quarter Alignment Used for Validation Affecting the FY 2024 Payment Determination	
Measures Submitted	**Required Quarters of Data for Validation**
Chart-Abstracted Measures	1Q 2021
	2Q 2021
	3Q 2021
	4Q 2021
eCQMs	1Q 2021 - 4Q 2021

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32840), we stated that we believe aligning the quarters of submission data used for both chart-abstracted measures and eCQM validation will allow hospitals selected for validation to more easily track and meet validation requirements, such as medical records requests from the CDAC.

We invited the public to comment on our proposal to incrementally align the quarters used for chart-abstracted measure and eCQM validation as previously discussed.

Comment: A commenter supported use of Q1–Q4 data for validation affecting FY 2024 payment determination and subsequent years because this would streamline the process and reduce hospital burden.

Response: We thank the commenter for this support.

Comment: A few commenters requested that CMS require fewer quarters for validation. A commenter expressed concern that requiring four quarters of data for validation of both chart-abstracted measures and eCQMs would be too high a burden. This commenter recommended that CMS require no more than two quarters for validation.

Response: While we agree with these commenters that restricting data validation to fewer calendar quarters may lead to some reduction to provider burden, we do not believe restricting data validation to fewer than two quarters would be consistent with our goals or approach, which has been designed to increase opportunities to detect poor reporting (77 FR 53540). Additionally, requiring fewer quarters of data for validation, which would reduce sample size, would impede the calculation of statistically significant validation scores needed to make payment determinations. We also note that the proposed increase in quarters for eCQM validation would occur in a gradual manner; hospitals would be validated on 2 quarters of CY 2021 eCQM data for validation affecting the FY 2024 payment determination, on 3 quarters of CY 2022 eCQM data for validation affecting the FY 2025 payment determination, and 4 quarters of CY 2023 eCQM data for validation affecting the FY 2026 payment determination and for subsequent years.

After consideration of the public comments that we received, we are finalizing our proposal as proposed to use Q1 through Q4 data of the applicable calendar year of both chart-abstracted measures and eCQMs for validation affecting FY 2024 payment determination and subsequent years.

c. Combination of Chart-Abstracted Measure and eCQM Validation Beginning With Validation Affecting the FY 2024 Payment Determination

As noted previously, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173), we finalized a separate validation process for eCQMs in the Hospital IQR Program. In addition to validating the chart-abstracted measures, we began validating an additional pool of up to 200 randomly selected hospitals for eCQMs (81 FR 57173).

Upon alignment of validation quarters as in section VIII.A.10.b.(2). of the preamble of this final rule, we wish to combine the validation process for both chart-abstracted measures and eCQMs. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to remove the separate process for eCQM validation, beginning with the validation affecting the FY 2024 payment determination (for validation commencing in CY 2022 using data from the CY 2021 reporting period) (85 FR 32840). Instead, beginning with validation affecting the FY 2024 payment determination and subsequent years, we proposed to incorporate eCQMs into the existing validation process for chart-abstracted measures such that there would be one pool of hospitals selected through random selection and one pool of hospitals selected using targeting criteria, for both chart-abstracted measures and eCQMs. Under the aligned validation process, a single hospital would be selected for validation of both eCQMs and chart-abstracted measures and would be expected to submit data for both chart-abstracted measures and eCQMs. For specific data submission requirements, we refer readers to section VIII.A.10.e of

[465] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

the preamble of this final rule ''Number of Cases Required for Validation.''

Comment: Several commenters supported alignment of validation processes between chart-abstracted measures validation, eCQM validation, and HAC Reduction Program validation. These commenters observed that this would reduce burden by improving coordination and allow hospitals to dedicate resources to patient care.

Response: We thank these commenters for their support.

Comment: A few commenters recommended that CMS delay combining the validation processes citing concerns about the current COVID–19 PHE.

Response: We acknowledge that currently many hospitals are being adversely affected by the COVID–19 PHE, and we do not wish to further burden these hospitals. However, our proposal to combine the eCQM and chart-abstracted validation processes begins with validation affecting the FY 2024 payment determination (that is, validation commencing in CY 2022 using data from the CY 2021 reporting period). We believe that this provides sufficient time for hospitals to prepare for the combined process.

Comment: A commenter requested that due to increased data submission requirements associated with having to submit chart-abstracted measure data, eCQM data, and HAC Reduction Program data, CMS extend the data submission timeframe to provide copies of the medical records from 30 days to 60 days.

Response: We do not believe that our proposals significantly increase the data submission requirements. We note that up until validation affecting the FY 2022 payment determination, when the HAC Reduction Program and Hospital IQR Program split validation approaches (83 FR 41482), hospitals selected for validation were already reporting HAC and chart-abstracted measure data. Furthermore, up through validation affecting the FY 2022 payment determination, hospitals reported a total of five chart-abstracted measures for validation (83 FR 41608); whereas, for validation affecting the FY 2023 payment determination and subsequent years, hospitals will only be reporting one chart-abstracted measure for validation (82 FR 38400). Because hospitals have previously been able to report these higher volumes of measures within the previously established validation data submission timeframe of 30-days (76 FR 51645 for chart-abstracted and 81 FR 57179 for eCQMs), we believe that the 30-day period continues to be appropriate.

Comment: A few commenters expressed concern regarding the effect of combining the HAC Reduction Program validation and the Hospital IQR Program's eCQM and chart-abstracted measure validation processes on payment determinations.

Response: We interpret the comment to mean that commenters are concerned that failing validation for the Hospital IQR Program or the HAC Reduction Program could lead to penalties under both programs. We are combining and aligning the hospital pool for the validation selection processes for the Hospital IQR Program and the HAC Reduction Program only. To be clear, these two programs will retain distinct and separate processes for validating submitted data, scoring, and applying any payment impacts to hospitals that fail validation. Failing Hospital IQR Program validation will not directly affect validation under the HAC Reduction Program, or vice versa.

Comment: A commenter recommended against adopting a combined validation process because of the belief that a consolidated process would be more burdensome than individual processes due to the multiple measure types affected by the new process.

Response: We are clarifying here that we are combining and aligning the hospital pool for the validation selection processes for the Hospital IQR Program and the HAC Reduction Program only. To be clear, these two programs will retain distinct and separate processes for validating submitted data, scoring, and applying any payment impacts to hospitals that fail validation. We refer readers to section VIII.A.10.f.2 below where we discuss the Hospital IQR Program validation process and section IV.M.6 where we discuss the HAC Reduction Program validation process in more detail. While there may be some instances of increased burden for specific hospitals, we disagree with the commenter that this approach is more burdensome for the majority of hospitals. Under previously established validation requirements, hospitals selected for validation were already required to submit medical records for both clinical process of care and HAI measures. While our proposed policy would add the requirement for hospitals selected for validation to also submit medical records for eCQMs, the number of requested medical records for eCQM cases (eight cases per quarter over two quarters for a total of 16 cases for validation affecting the FY 2024 payment determination) remains low relative to clinical process of care cases (8 cases per quarter, over four quarters) and HAI cases (10 cases per quarter, over four quarters), that will be required for validation affecting the FY 2024 payment determination. Combining and aligning the hospital pool for validation between the programs would reduce burden by 400 hospitals per year starting with validation affecting the FY 2024 payment determination. This is supported by the majority of comments that we received in response to this proposal, which indicate that most hospitals believe that the combined process will be less burdensome. In addition, as discussed further below, we also proposed to reduce the overall number of hospitals selected for validation from 800 to up to 400, which reduces the overall validation burden.

(1) Targeted Selection of Hospitals for Validation

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50834) where we finalized targeted chart-abstracted measure validation for a supplemental sample of hospitals in addition to random validation. The supplemental sample of hospitals includes all hospitals that failed validation in the previous year and a random sample of hospitals meeting certain targeting criteria. These criteria are as follows:

- Any hospital with abnormal or conflicting data patterns. One example of an abnormal data pattern would be if a hospital has extremely high or extremely low values for a particular measure. As described in the FY 2013 IPPS/LTCH PPS final rule, we define an extremely high or low value as one that falls more than 3 standard deviations from the mean which is consistent with the Hospital OQR Program (76 FR 74485). An example of a conflicting data pattern would be if two records were identified for the same patient episode of care but the data elements were mismatched for primary diagnosis. Primary diagnosis is just one of many fields that should remain constant across measure sets for an episode of care. Other examples of fields that should remain constant across measure sets are patient age and sex. Any hospital not included in the base validation annual sample and with statistically significantly more abnormal or conflicting data patterns per record than would be expected based on chance alone ($p < .05$), would be included in the population of hospitals targeted in the supplemental sample.
- Any hospital with rapidly changing data patterns. For this targeting criterion, we define a rapidly changing

data pattern as a hospital which improves its quality for one or more measure sets by more than 2 standard deviations from 1 year to the next, and also has a statistically significant difference in improvement (one-tailed p < .05) (77 FR 53553).

- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.
- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated.
- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.
- Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed that beginning with validation affecting the FY 2024 payment determination, the existing targeting criteria would apply to all applicable hospitals, capturing both measure types (that is, chart-abstracted measures and eCQMs) (85 FR 32841). In other words, we proposed to expand targeted validation to include eCQMs, not just chart-abstracted-measures. We stated that doing so will facilitate the proposed combination of chart-abstracted and eCQM validation such that hospitals selected under this combined targeting approach would be validated for both chart-abstracted and eCQMs.

Additionally, we clarified that a hospital that has been granted an Extraordinary Circumstances Exception could still be selected for validation (chart-abstracted measures and eCQMs) under the targeting criteria. We invited public comment on our proposal.

Comment: Several commenters supported aligning hospital selection for eCQMs, HAC Reduction Program, and Hospital IQR Program chart-abstracted measure validation, including applying the existing targeted criteria.

Response: We thank these commenters for their support.

Comment: Several commenters expressed concern regarding the proposal to allow hospitals granted ECEs to be selected for validation. A commenter observed that ECEs represent potential operational disruptions to hospitals which could impact validation. A commenter recommended that CMS retain this exclusion. Another commenter recommended that CMS defer validation for hospitals that have been granted an ECE until the first validation period following the expiration of the ECE.

Response: The validation process requires hospitals to submit charts to support data they submitted during an applicable reporting period. If a hospital was granted an ECE and did not report data for the applicable reporting period, the hospital would not submit data on any cases and, therefore, there would be no cases for the hospital to support through submission of medical charts for validation. This would not affect the hospital's validation score. In the case that validation is occurring during a period excepted by an ECE applicable to data submitted prior (that is, validation requests that are sent to hospitals during an ECE period for data reporting periods that occurred prior to the ECE), we believe that the importance of ensuring the validity of publicly reported data (which reflects care provided prior to the extraordinary circumstance) may be sufficient to require hospitals to submit charts for validation during that period. However, we acknowledge the commenters' concern and will consider extending the validation data submission period in future rulemaking.

After consideration of the public comments, we are finalizing our proposal as proposed to apply our existing targeting criteria to all applicable hospitals, capturing both measure types (that is, chart-abstracted measures and eCQMs).

(2) Number of Hospitals

In the FYs 2013 and 2014 IPPS/LTCH PPS final rules (77 FR 53551 through 53554 and 78 FR 50833), we finalized that for chart-abstracted measure validation, we take an annual sample from 400 randomly selected hospitals and from up to 200 hospitals selected using targeting criteria. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57178), we finalized that for eCQMs, we take an annual sample of up to 200 randomly selected hospitals that have not been selected for chart-abstracted measure validation. Under these existing policies, we may validate data from up to a total of 800 hospitals for a given year for both chart-abstracted measures and eCQMs.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to change the hospital selection policies to reduce the total number of hospitals selected for validation from up to 800 hospitals to up to 400 hospitals, beginning with validation affecting the FY 2024 payment determination (85 FR 32841). We proposed that up to 200 hospitals would be selected randomly and up to 200 would be selected using targeted criteria. Here, we summarize and respond to general comments. Detailed descriptions on proposals to effectuate that reduction and related comments and responses follow further below.

Comment: Several commenters supported the reduction from 800 hospitals to up to 400 hospitals to be selected for validation. Some of these commenters observed that this would reduce administrative burden and others observed that it would allow hospitals to focus resources on patient focused activities.

Response: We thank these commenters for their support.

Comment: Several commenters expressed concern that reducing the number of hospitals selected for validation may lead to too small a sample size to ensure data validity.

Response: We recognize that a smaller sample size may impact the reliability of the data. However, as we noted in the proposed rule, based on the expected percentage of hospitals passing validation (which we estimated at 96 percent based on values from validation affecting the FY 2018, FY 2019, and FY 2020 payment determinations, which were 96.4 percent, 95.8 percent, and 96.2 percent respectively), our power calculation indicates that with a pool of up to 200 hospitals, we can be highly confident that at least 94.8 percent of all hospitals in the Hospital IQR Program population are achieving the requisite reliability score. We will continue to monitor the number of hospitals passing validation and if the pass rate falls to a level where we can no longer be confident in the reliability scores of hospitals in the Hospital IQR Program population, we will address this issue in future rulemaking.

Comment: A few commenters recommended further reducing the number of selected hospitals to further reduce burden, especially due to the burden of COVID–19 on hospitals.

Response: Because the minimum sample size required to assess the percentage of hospitals in the Hospital IQR Program depends on the expected percentage of hospitals that fail validation, we do not believe that we can reduce the number of selected hospitals below the proposed amount of up to 400 at this time. However, we will continue to evaluate the number of hospitals required to be statistically confident that hospitals in the Hospital IQR Program population are achieving the requisite reliability score.

(a) Number of Hospitals Under Random Selection

Instead of taking an annual sample from 400 randomly selected hospitals as

previously finalized, we proposed to reduce the number of hospitals selected at random for validation to up to 200 hospitals, beginning with validation affecting the FY 2024 payment determination (measure data collected during CY 2021 and submitted during CY 2022 for the FY 2023 payment determination). We proposed these changes in conjunction with the HAC Reduction Program and refer readers to section IV.M. of this final rule for those proposals. We believe that reducing the total number of hospitals selected for chart-abstracted measure validation each year to ''up to 200'' would maintain a sufficient sample size for a statistically meaningful estimate of hospitals' reporting accuracy and help streamline the process for both programs.

One of our goals for the annual random sample is to estimate the total percentage of hospitals in the Hospital IQR Program that have been reporting unreliable data. The basic premise behind random sampling is that one can learn something about all hospitals by gathering data on just a subset of hospitals (77 FR 53552). The minimum sample size required to assess the percentage of hospitals in the Hospital IQR Program that have been reporting unreliable data depends on the expected percentage of hospitals that fail validation. Because a very high percentage of Hospital IQR Program hospitals pass validation (96.4 percent for the FY 2018 payment determination, 95.8 percent for the FY 2019 payment determination, and 96.2 percent for the FY 2020 payment determination), we believe that we can reduce burden on hospitals by selecting fewer hospitals for the base annual random sample without adversely affecting our estimate of this percentage. Using an estimated passing rate of 96 percent, our power calculations indicate that with a pool of up to 200 hospitals, we can be highly confident that at least 94.8 percent of all hospitals in the Hospital IQR Program population are achieving the requisite reliability score.

In addition, in the FY 2019 IPPS/LTCH PPS final rule, we finalized removal of five healthcare associated infection measures [466] from the Hospital IQR Program and incorporated the same measures into the HAC Reduction Program (83 FR 41547 through 41553). Because of this, in the FY 2019 IPPS/LTCH PPS final rule, we also created validation policies under the HAC Reduction Program (83 FR 41479 through 41483). Following the transfer of NHSN HAI measure validation to the HAC Reduction Program, we are proposed that both the Hospital IQR Program and the HAC Reduction Program use a single random hospital sample of up to 200 hospitals beginning with validation affecting the FY 2024 payment determination. In other words, hospitals would be randomly selected and this pool of up to 200 hospitals would be validated under both programs.

In the FY 2021 IPPS/LTCH PPS proposed Rule, we proposed to change the Hospital IQR Program policy from an exact number of hospitals selected for random validation (that is, 400) to a range (that is, up to 200) (85 FR 32842). This is because there are some hospitals that are eligible for the HAC Reduction Program, but which do not also participate in the Hospital IQR Program. Over 95 percent of hospitals that are eligible for the HAC Reduction Program also participate in the Hospital IQR Program. The small proportion of hospitals that do not participate in the Hospital IQR Program would be included in the single pool from which hospitals could be randomly selected; however, if such a hospital were selected for validation, it would not be required to submit data for validation under the Hospital IQR Program. Therefore, selecting a single sample for both programs could potentially result in a number totaling less than 200 hospitals for validation of Hospital IQR Program chart-abstracted data because hospitals that are eligible for the HAC Reduction Program, but do not participate in the Hospital IQR Program would not be validated in the Hospital IQR Program. This is consistent with the previously finalized Hospital IQR Program chart-abstracted validation process, for which hospitals were subject to both chart-abstracted measure validation as well as HAI measure validation (83 FR 41608). The only difference is that HAI measure validation has since moved to the HAC Reduction Program and, hence, the HAI validation performance will be accounted for under the HAC Reduction Program.

We stated our belief that this proposal will simplify validation for hospitals under both programs and enable us to continue validating Hospital IQR Program chart-abstracted data without increasing the total number of hospitals selected for validation across both programs. We also refer readers to section IV.M. of the preamble of this final rule for more detail on the validation proposals for the HAC Reduction Program. Again, we note that this proposal is being made in conjunction with that in the HAC Reduction Program, and finalization of this proposal in the Hospital IQR Program would be contingent on the HAC Reduction Program proposal also being finalized.

We invited public comment on this proposal.

Comment: A commenter requested clarification regarding how the HAC Reduction Program validation process would apply to hospitals selected for Hospital IQR Program validation. This commenter observed that the validation process for the HAC Reduction Program is described in a separate rule section and noted that this could lead to confusion regarding how the two processes interact.

Response: We are clarifying here that we are combining and aligning the hospital pool for the validation selection processes for the Hospital IQR Program and the HAC Reduction Program only. To be clear, these two programs will retain distinct and separate processes for validating submitted data, scoring, and applying any payment impacts to hospitals that fail validation. The Hospital IQR Program will validate these hospitals' data using the methodology laid out in this section; the HAC Reduction Program will validate these hospitals' data using the methodology described in section IV.M of the preamble of this final rule.

After consideration of the public comments, we are finalizing our proposal as proposed to change the Hospital IQR Program policy from an exact number of hospitals selected for random validation (that is, 400) to a range (that is, up to 200). We refer readers to section M.6 of this final rule where we are also finalizing similar policies under the HAC Reduction Program.

(b) Exclusion Criteria

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38399), we finalized exclusion criteria, applied before the random selection of up to 200 hospitals for eCQM validation. The exclusion criteria include any hospital—

- Selected for chart-abstracted measure validation;
- That has been granted an Extraordinary Circumstances Exception (ECE); and
- That does not have at least five discharges for at least one reported eCQM included among their QRDA I file submissions (81 FR 57174 and 82 FR 38399).

Hospitals meeting one or more of these exclusion criteria are not eligible for selection for eCQM validation each year (82 FR 38399).

[466] CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia.

In the FY 2021 IPPS/LTCH PPS proposed rule, in conjunction with our proposal to combine chart-abstracted measure and eCQM validation, we proposed to remove all of the previously finalized exclusion criteria (as previously referenced) beginning with validation affecting the FY 2024 payment determination and for subsequent years (85 FR 32842). Since a separate sample of hospitals for eCQM validation will no longer need to be identified, the previously finalized exclusion criteria for eCQM validation hospital selection will no longer be needed. We invited public comment on our proposal to remove the previously finalized exclusion criteria. We stated that finalization of this proposal would be contingent on finalization of our proposal to combine chart-abstracted measure and eCQM validation.

Comment: A few commenters requested clarification regarding how the existing exclusion criteria, particularly the exclusion of hospitals from selection for eCQM validation if they have been granted an ECE, apply to the consolidated validation process.

Response: We refer readers to the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49695) for our policies regarding ECEs for eCQM issues. Our regulations at 42 CFR 412.140 state that CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the hospital. Specific requirements for submission of a request for an exception are available on *QualityNet.org.* In the FY 2016 IPPS/LTCH PPS Final Rule, we stated that our targeting criteria permits that a hospital may be selected for chart-abstracted validation even if it has been granted an ECE with respect to one or more chart-abstracted measures for the applicable data collection period (81 FR 57174). Our previous policy was that if a hospital was granted an ECE with respect to eCQM reporting for the applicable eCQM reporting period, the hospital would be excluded from the eCQM validation sample due to its inability to supply data for validation (81 FR 57174). In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32842), we proposed to remove this exclusion in light of our proposal to combine chart-abstracted measure and eCQM validation. While such hospitals may be unable to supply eCQM data, we believe they would continue to be able to supply HAI and chart-abstracted measure data for validation of these measures. We note that hospitals that have been granted ECEs for any general reason have not previously been automatically excluded from being selected for chart-abstracted or HAI measure data validation (77 FR 53552 through 53553), and this continues to be the case. However, because the consolidated validation process will apply across multiple data types, we no longer believe that these exclusions are necessary. A hospital affected by an ECE related to eCQM reporting may be unable to supply data regarding eCQMs however, we believe it would still be able to supply data for validation of the HAIs and chart-abstracted measures as they have been required to under our existing policies.

Comment: A commenter requested that CMS clarify whether a hospital would be excluded from validation if it did not have at least five discharges for at least one reported eCQM included among its QRDA I file submissions.

Response: We do not believe this or any of the other previously established exclusion criteria are needed because these exclusion criteria were established for hospitals that may not have data for eCQM validation. Because we are finalizing our proposal to combine chart-abstracted measure and eCQM validation in section VIII.A.10.f, below, we believe that even if hospitals do not have data to submit for eCQM validation, they should have data to submit for chart-abstracted measure validation, and therefore, should be eligible to be selected for validation. After consideration of the public comments, we are finalizing our proposal as proposed to remove all of the previously finalized exclusion criteria beginning with validation affecting the FY 2024 payment determination and for subsequent years.

(c) Number of Hospitals Selected Under Targeted Selection

We refer readers to FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553) where we previously established that we would select up to 200 hospitals for chart-abstracted measures data validation using the targeting criteria described in section VIII.A.11.c. of the preamble of this final rule. The Hospital IQR Program does not currently have a policy for targeted selection of hospitals for eCQM validation.

In the FY 2021 IPPS/LTCH PPS proposed rule, while we did not propose any changes to the number of hospitals selected using targeting criteria (see sections VIII.A.3.c.(1) and VIII.A.10.a. of this final rule), we proposed to combine chart-abstracted measure and eCQM validation and to decrease the number of randomly selected hospitals (85 FR 32842 through 32843); we also refer readers to sections VIII.A.3.c.(1) and VIII.A.10.a above where these are discussed. If these proposals are both finalized, the total number of hospitals selected for validation (for both chart-abstracted measures and eCQMs) would be at maximum 400 (up to 200 hospitals randomly selected + up to 200 hospitals using targeting criteria). The current and proposed validation hospital numbers and measure types are illustrated in the tables that follow:

Current Validation Process		
Selection Process	**Number of Hospitals**	**Measure Type**
Random Selection	400	Chart-Abstracted
Targeted Selection	Up to 200	Chart-Abstracted
Random Selection	Up to 200	eCQMs
Total:	Up to 800	

Validation Process Beginning with Validation Affecting the FY 2024 Payment Determination		
Selection Process	Number of Hospitals	Measure Type
Random Selection	Up to 200	Chart-Abstracted and eCQM
Targeted Selection	Up to 200	Chart-Abstracted and eCQM
Total:	Up to 400	Chart-Abstracted and eCQM

Under the aligned validation process we are finalizing in this final rule, the Hospital IQR Program would validate a pool of up to 400 hospitals (up to 200 randomly selected and up to 200 selected using the targeting criteria), across both measure types.

d. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests Beginning With Validation Affecting the FY 2024 Payment Determination

Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation (75 FR 50226), or they may submit copies of medical records for validation by securely transmitting electronic versions of medical information (78 FR 50834 and 79 FR 50269). Submission of electronic versions can either entail downloading or copying the digital image of the medical record onto CD, DVD, or flash drive (78 FR 50835), or submission of PDFs using a secure file transmission process after logging into the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System) (79 FR 50269). We reimburse hospitals at $3.00 per chart (78 FR 50956). Neither paper copies nor submission of CD, DVD, or flash drive is applicable for eCQMs since that data is required to be submitted electronically via Secure File Transfer (81 FR 57174 through 57178).

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to discontinue the option for hospitals to send paper copies of, or CDs, DVDs, or flash drives containing medical records for validation affecting the FY 2024 payment determination (that is, beginning with data submission for Q1 of CY 2021) (85 FR 32843). We proposed to require hospitals to instead submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the FY 2024 payment determination (that is, Q1 of CY 2021) and for subsequent years. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process. We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts.

We strive to provide the public with accurate quality data while maintaining alignment with hospital recordkeeping practices. We appreciate that hospitals have rapidly adopted EHR systems as their primary source of information about patient care, which can facilitate the process of producing electronic copies of medical records (78 FR 50834). Additionally, we monitor the medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor, and have found that almost two-thirds of hospitals already use the option to submit PDF copies of medical records as electronic files. In our assessment based on this monitoring, we believe requiring electronic file submissions can be a more effective and efficient process for hospitals selected for validation. Requiring electronic file submissions reduces the burden of not only coordinating numerous paper-based pages of medical records, but also of having to then ship the papers or physical digital media storage to the CDAC. Therefore, we believe it is appropriate to require that hospitals use electronic file submissions via a CMS-approved secure file transmission process. We invited public comment on our proposal.

Comment: Several commenters supported the proposal to require hospitals to submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures. A commenter noted that requiring electronic files will reduce administrative burden.

Response: We thank the commenters for their support and agree that the proposal will reduce administrative burden.

Comment: A few commenters supported the proposal, but expressed concern that requiring electronic file submissions for chart-abstracted measure validation will be burdensome given the COVID–19 public health emergency (PHE) and asked CMS to delay this requirement. A commenter expressed concern that the influenza season and potential increased COVID–19 case counts in fall 2020 would make it more difficult for facilities to implement such a change and asked that the proposal be delayed by one year. In the meantime, the commenter suggested reducing the reimbursement rate for the paper-based submissions to encourage electronic submissions and reduce the cost to CMS of administering the program.

Response: We appreciate the commenters support for the proposal and recognize that some organizations do not submit validation data electronically and therefore will need to update their processes if they are selected for validation. However, we believe that the relative security of electronic submission versus mailing paper records outweighs the effort of updating processes. Furthermore, we believe that the reduced effort of printing, packaging, and mailing records

will offset the burden of updating processes and reduce the impact of potential shipping delays on validation Based on our monitoring of medical record submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor, we believe requiring electronic file submissions is a more effective and efficient process and will reduce burden for hospitals selected for validation, which we believe to be especially critical during the COVID–19 PHE and a potential increase in volume of influenza cases. We appreciate the commenter's suggestion to reduce reimbursement for paper charts to incentivize transition to electronic records, however, we believe that the efficiencies of electronic data submission outweigh any benefits to delaying this change.

Comment: A commenter expressed concern that PDF copies of some patient files may take a long time to upload to Secure File Transfer and cause the application to time out. The commenter suggested a work around should any upload errors occur. Another commenter stated their belief that PDF files cannot be easily extracted without further processing or formatting and that interoperability requires that information be exchanged using common data standards to facilitate coordinated care and improved outcomes. This commenter encouraged CMS to develop and implement an industry-wide open application program interface (API) standard.

Response: We appreciate the commenters' concerns and will monitor the PDF upload process, and if needed, modify the process or consider improvements for future rulemaking. We believe that requiring PDF file submissions will ultimately decrease burden.

Comment: A commenter asked if the format for CMS's validation request to hospitals will be modified and if all communication between the hospital and CMS for the validation process will be electronic.

Response: We have not proposed any changes to the formats of the validation request or other communications in the validation process.

After consideration of the public comments, we are finalizing our proposal as proposed to require hospitals to submit only electronic files when submitting copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the FY 2024 payment determination (that is, Q1 of CY 2021) and for subsequent years. Under this policy, hospitals would be required to submit PDF copies of medical records using direct electronic file submission via a CMS approved secure file transmission process. We will continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts.

e. Number of Cases Required for Validation

(1) Chart-Abstracted Measures

We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 through 57180) where we established a process in which the CDAC contractor requests selected hospitals to submit eight randomly selected medical records on a quarterly basis from which data are abstracted (for a total of 32 records per year). Once the CDAC contractor receives the data, it re-abstracts the measures which were submitted by the hospitals for the Hospital IQR Program and calculates the percentage of matching measure numerators and denominators for each measure within each chart submitted by the hospital. Each selected case may have multiple measures included in the validation. We did not propose any changes to the number of cases required from each selected hospital for chart-abstracted measure validation.

(2) eCQMs

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38399), we finalized that selected hospitals must submit eight cases per reported quarter to complete eCQM data validation. We consider a sample of eight cases per quarter to be the minimum sample size needed to accurately ascertain the quality of the reported data (82 FR 38399). Each selected case may have multiple measures included in the validation.

In the FY 2021 IPPS/LTCH PPS proposed rule, we did not propose any changes to this policy. However, we refer readers to section VIII.A.10.e. of the preamble (Reporting and Submission Requirements for eCQMs) of this final rule for more details on our finalized proposal to increase the number of quarters for which hospitals are required to report eCQM data: From one self-selected quarter of data to four quarters of data progressively over several years. With the finalization of the increased eCQM reporting quarters, hospitals selected for validation will be required to submit: (1) A total of 16 requested cases from 2 calendar quarters of CY 2021 eCQM data (8 cases × 2 quarters) for validation affecting the FY 2024 payment determination; (2) a total of 24 requested cases from 3 quarters of CY 2022 eCQM data (8 cases × 3 quarters) for validation affecting the FY 2025 payment determination; and (3) a total of 32 requested cases over 4 quarters of data (8 cases × 4 quarters), starting with validation of CY 2023 eCQM data, for validation affecting the FY 2026 payment determination and for subsequent years. This means that for eCQM validation, hospitals will have to submit validation data for each quarter of their self-selected eCQM submission quarters.

f. Scoring Processes

(1) Current Scoring Process

Currently, there are two separate processes for payment determinations related to validation requirements—one for chart-abstracted measure validation and another for eCQM validation.

For chart-abstracted measure validation scoring, under the current process, the CDAC contractor requests that hospitals submit eight randomly selected medical records on a quarterly basis from which data are abstracted and submitted by the hospital to the Clinical Data Warehouse (for a total of 32 records per year per hospital). Once the CDAC contractor receives the data, it re-abstracts the same data submitted by the hospitals and calculates the percentage of matching measure numerators and denominators for each measure within each chart submitted by the hospital (81 FR 57179 through 57180). Each selected case may have multiple measures included in the validation score. Specifically, one patient may meet the numerator and denominator criteria for multiple measures, and therefore, would generate multiple measures in the validation score. Consistent with previous years, each quarter and clinical topic is treated as a stratum for variance estimation purposes. Approximately 4 months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). At the end of the year, the validation score is calculated by combining the data from all four quarters into one agreement rate for each hospital. At this point, we calculate a confidence interval around the agreement rate for each hospital using a normal distribution assumption. The upper bound of the confidence interval is calculated as the final validation score. A hospital must attain at least a 75 percent validation score based upon all four quarters of chart-abstracted data validation to pass the validation requirement. The overall

validation score from the chart-abstracted measure is used to determine whether a hospital has met the validation requirement under the Hospital IQR Program for purposes of the annual payment update. Specifically, if a hospital fails chart-abstracted validation (because the validation score was below 75 percent), it would receive an applicable annual reduction to the hospital's IPPS market basket update (APU) for failing to meeting all Hospital IQR Program requirements.

eCQM validation is different, because the accuracy of eCQM data submitted for validation (as measured by the agreement rate) does not currently affect a hospital's payment determination as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181). As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38399), selected hospitals must submit eight cases, per self-selected quarter to complete eCQM data validation. Because the reporting quarter is self-selected, validation occurs on an annual basis using all 8 cases that are submitted. For hospitals to receive their full APU, they must provide at least 75 percent of requested eCQM medical records in a timely and complete manner (82 FR 38398 through 38401). Hospitals receive eCQM validation results through email communications on an annual basis.[467]

(2) Weighted Scoring

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32844), we proposed to provide one combined validation score starting with validation affecting the FY 2024 payment determination and for subsequent years. Specifically, this single score would reflect a weighted combination of a hospital's validation performance for chart-abstracted measures and eCQMs. Since eCQMs are not currently validated for accuracy, we proposed that the eCQM portion of the combined agreement rate would be multiplied by a weight of zero percent and chart-abstracted measure agreement rate would be weighted at 100 percent for validation affecting the FY 2024 payment determination and subsequent years (that is, starting with the CY 2021 discharge data submitted for FY 2023 payment determination and validation affecting the FY 2024 payment determination). The agreement rate and associated confidence interval would be calculated based on the validation data collected from each hospital for each fiscal year. The validation score associated with the combined agreement rate would be the upper bound of the calculated confidence interval. For more detailed information on the confidence interval, please refer to the Chart-Abstracted Data validation page of QualityNet: *https://www.qualitynet.org/inpatient/data-management/chart-abstracted-data-validation*. Under this policy, however, in the absence of an eCQM score that reflects reporting accuracy, hospitals would continue to be required to successfully submit at least 75 percent of the requested medical records for eCQM validation. Submission of requested medical records at or in excess of this threshold would meet the eCQM validation requirements. Under this proposal, hospitals would continue to receive their total validation score annually.

As we move forward, we will determine when eCQM measure data are ready for accuracy scoring for validation. We have progressively increased the number of eCQM validation cases (from 8 cases for validation affecting FY 2023 payment determination, to 16 cases for validation affecting FY 2024 payment determination, to 24 cases for validation affecting FY 2025 payment determination, and to 32 cases for validation affecting FY 2026 payment determination and beyond). The additional cases collected and validated under the proposal will support the calculation of a statistically robust validation score. We anticipate increasing the eCQM validation score weighting in the future to include eCQM measures accuracy as part of the overall validation score. Any adjustments in the weighting and scoring would be proposed through future rulemaking. We invited public comments on our proposal.

Comment: A few commenters supported the proposal to provide a single weighted validation score in which the eCQM portion of the score would be multiplied by a weight of zero percent and chart-abstracted measure agreement rate would be weighted at 100 percent. A few of these commenters encouraged CMS to continue weighting the eCQM score at zero until hospitals have become accustomed to reporting more than one self-selected quarter of data and to the updated validation process.

Response: We thank commenters for their support and plan to determine when eCQM measure data are ready for accuracy scoring for validation as we move forward. Any adjustments to the validation process, including weighting or the method for calculating scores, would be proposed through future rulemaking.

Comment: A commenter opposed the proposal to weigh the eCQM portion of the combined agreement rate at zero percent and the chart-abstracted measure portion of the agreement rate at 100 percent. The commenter argued that such a weighting would formalize that eCQMs can be less accurate measures, and therefore, would not serve the purpose of validation. The commenter recommended developing a validation process and scoring system that consistently identifies and educates on measurement errors regardless of whether these errors are in chart-abstracted data or electronically captured in the EHR.

Response: Currently, the accuracy of eCQM data submitted for validation does not affect a hospital's payment determination as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181). The proposal to weight the eCQM portion of the combined agreement rate at zero percent takes this existing policy into account and is therefore not a change in policy regarding the scoring of eCQM data for accuracy. Therefore, we disagree with commenters that we are formalizing that eCQMs can be less accurate measures, rather we believe that it continues to serve to allow hospitals and their vendors to become proficient in collecting and reporting eCQM data. We appreciate the commenter's recommendation and anticipate increasing the eCQM validation score weighting in the future to include eCQM accuracy as part of the overall validation score. We reiterate that any adjustments in the weighting and scoring of validation scores would be proposed through future rulemaking. We refer readers to section VIII.A.10.h.ii below where we are finalizing an educational review process for eCQMs, which will provide an opportunity for hospitals to ask questions and better understand their eCQM validation results in addition to the established educational review procedures for chart-abstracted measures.

Comment: A few commenters expressed concern that CMS would increase the weight of the eCQM validation score without ensuring the eCQM validation process has a level of rigor and transparency comparable to that of validation of chart-abstracted measures. These commenters recommended improving the eCQM validation process by (1) providing more detailed information in validation

[467] *https://qualitynet.org/inpatient/data-management/ecqm-data-validation.*

reports about the causes of a mismatch; (2) developing transparent, consistent criteria for where in medical records CMS's validators look for information; and (3) gradually increasing any requirement for eCQM accuracy slowly over time. Several commenters provided specific recommendations regarding the eCQM validation process including: (1) Developing a process based on QRDA I data; (2) accounting for mid-year eCQM specification changes; (3) publishing eCQM validation data; and (4) ensuring that the team validating eCQM data understands the differences between eCQM abstraction and chart abstraction. A commenter recommended that CMS convene stakeholders to address the issue of eCQM validation.

Response: We acknowledge commenters' concerns and thank them for their recommendations. We refer readers to section VIII.A.12.b.(1). below, where we discuss our eCQM validation development in more detail. We are continually working to improve our validation processes including developing improved validation reports. Furthermore, our intent is to increase requirements for eCQM accuracy gradually over time from our current weighting of zero percent. Additionally, we note that we provide the same information to hospitals and to our validation team regarding measure specifications, and therefore we believe that we have provided sufficient information regarding where within medical records abstractors look for information. We will take these concerns and suggestions into consideration as we continue to evaluate and develop our eCQM validation policies and processes. We reiterate that any adjustments in the weighting and validation scoring would be proposed through future rulemaking. We believe that the expanded educational review process described in section VIII.A.10.h.ii. below will increase the transparency of the eCQM validation process which will allow stakeholders to better comment on the rigor of this process at such a time as we propose to increase the weight.

Comment: A few commenters requested that CMS delay its proposal to provide a combined validation score for eCQM and chart-abstracted measure validation. These commenters noted that, unlike chart-abstracted measure validation, eCQM validation does not currently account for the accuracy of the submissions, rather eCQM validation is scored based on submission of the data. These commenters recommended delaying the proposal to combine eCQM and chart-abstracted measure validation until an eCQM validation process that incorporates accuracy of eCQM data is developed and validated.

Response: We acknowledge that our proposed policy does not currently reflect validation of eCQMs' accuracy, but believe that our proposal adequately addresses the commenters' concerns by weighing the eCQM portion of the combined agreement rate at zero percent for the time being. We refer readers to section VIII.A.12.b.(1). below, where we discuss our eCQM validation development in more detail. Based on our experience, we believe a gradual, step-wise approach is beneficial. As we move forward, we will use the results of these eCQM validation efforts to inform future policy-making for when eCQM measure data are ready for accuracy scoring for validation and when an increase in weighting is warranted. Thus, we do not believe we should delay our proposal.

After consideration of the public comments, we are finalizing our proposal as proposed to provide one combined validation score starting with validation affecting the FY 2024 payment determination and for subsequent years. Specifically, this single score would reflect a weighted combination of a hospital's validation performance for chart-abstracted measures and eCQMs. Since eCQMs are not currently validated for accuracy, the eCQM portion of the combined agreement rate will be multiplied by a weight of zero percent and chart-abstracted measure agreement rate will be weighted at 100 percent for validation affecting the FY 2024 payment determination and subsequent years (that is, starting with the CY 2021 discharge data submitted for FY 2023 payment determination and validation affecting the FY 2024 payment determination).

g. Summary

Our validation proposals are summarized in the following table:

	Quarters of Data Required for Validation	Scoring
Finalized Process for Validation Affecting the FY 2023 Payment Determination		
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020	At least 75% validation score
	4Q 2020	
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 - 4Q 2020	Successful submission of at least 75% of requested medical records
Finalized Process for Validation Affecting the FY 2024 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 - 4Q 2021	Chart-abstracted Measures: At least 75% validation score (weighted at 100%) And eCQMs: Successful submission of at least 75% of requested medical records

h. Educational Review Process

(1) Chart-Abstracted Measures

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50260), we established an educational review process for validation of chart-abstracted measures. The process was subsequently updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38403). In this process, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation results. As noted previously, approximately 4 months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality

Reporting (HQR) System). Hospitals have 30 calendar days following the date validation results are posted to identify any potential CDAC or CMS errors for the first three quarters of validation results and contact the Validation Support Contractor (VSC) to request an educational review. Upon receipt of an educational review request, we review the data elements identified in the request, as well as the written justifications provided by the hospital. We provide the results of an educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through a CMS-approved secure file transmission process (82 FR 38402). We note that at the end of the year, the validation score is calculated by combining the data from all four quarters into one agreement rate for each hospital.

If an educational review yields incorrect CMS validation results for chart-abstracted measures, we use the corrected quarterly score, as recalculated during the educational review process to compute the final confidence interval (82 FR 38402). We use the revised score identified through an educational review when determining whether or not a hospital failed validation (82 FR 38402). Corrected scores, however, are only used if they indicate that the hospital performed more favorably than previously determined (82 FR 38402).[468] We note that corrections only occur to calculations, not to the underlying measure data (82 FR 38402). A detailed description of the educational review process for validation of chart-abstracted measures is also available on the QualityNet website. We did not propose any changes to our educational review process for chart-abstracted measures.

(2) Educational Review Process for eCQMs for Validation Affecting the FY 2023 Payment Determination and Subsequent Years

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32845), we proposed to extend a similar process established for chart-abstracted measure validation educational reviews to eCQM validation beginning with validation affecting the FY 2023 payment determination and subsequent years (that is, starting with data from CY 2020). While we proposed and are finalizing combining the hospital pool and generating a single score for both eCQM and chart-abstracted measure data validation, these underlying processes would still remain distinct because the underlying data being validated is distinct. We believe that expanding the educational review process to incorporate eCQMs would allow hospitals to better understand the processes and data for eCQM validation. Under our proposal, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation of eCQMs. Specifically, a hospital would have 30 calendar days to contact the VSC to solicit a written explanation of the validation performance following the date that the validation results were provided to the hospital. Because hospitals receive eCQM validation results on an annual basis, however, they would have the opportunity to request an educational review once annually following receipt of their results. Upon receipt of an educational review request, we would review the requested data elements and written justifications provided by the hospital. We also proposed to provide the results of the eCQM validation educational review to the requesting hospital, outlining the findings of whether the scores were correct or incorrect, through a CMS-approved secure file transmission process.

We invited public comment on our proposal.

Comment: Several commenters supported the proposal to extend the educational review process established for chart-abstracted measure validation to eCQM validation.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal as proposed to extend a similar process established for chart-abstracted measure validation educational reviews to eCQM- validation beginning with validation affecting the FY 2023 payment determination and subsequent years (that is, starting with data from CY 2020).

11. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We did not propose any changes to this policy.

12. Public Display Requirements

a. Background

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the *Hospital Compare* and/or its successor website after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* website at: *http://www.medicare.gov/hospitalcompare*, or on other CMS websites such as: *https://data.medicare.gov,* or their successor websites.

b. Public Reporting of eCQM Data

(1) Background

The Hospital IQR Program initiated voluntary reporting of eCQM data in the FY 2014 IPPS/LTCH PPS final rule, for the CY 2014 reporting period/FY 2016 payment determination (78 FR 50807 through 50810). At that time, we noted our belief that electronic collection and reporting of quality data using health IT would ultimately simplify and streamline quality reporting (78 FR 50807). Based on our ongoing experience with eCQMs, we continue to believe this. We also believe that electronic reporting furthers CMS and HHS policy goals to promote quality through performance measurement and, in the long-term, will both improve the accuracy of the data and reduce

[468] Hospitals may still request reconsideration even if an educational review determined that a hospital was scored correctly. Hospitals that fail Hospital IQR Program requirements, including validation, may request reconsideration after receiving notification of their payment determination for the applicable fiscal year.

reporting burden for providers. We expect that over time, hospitals will continue to leverage EHRs to capture, calculate, and electronically submit quality data, build and refine their EHR systems, and gain more familiarity with reporting eCQM data (78 FR 50807).

Since the FY 2014 IPPS/LTCH PPS final rule, the Hospital IQR Program's eCQM reporting requirements have evolved. In the FY 2016 IPPS/LTCH PPS final rule, the reporting of eCQM data became required (rather than voluntary) under the Hospital IQR Program, beginning with the CY 2016 reporting period/FY 2018 payment determination (80 FR 49693 through 49698). At the time of publication of this final rule, hospitals will have completed the reporting of eCQM data for the CY 2019 reporting period/FY 2021 payment determination by the March 2, 2020 submission deadline, the fourth year of required eCQM reporting.

Most recently, in the FY 2020 IPPS/PPS LTCH final rule, we finalized the Hospital IQR Program's reporting requirements for the CY 2022 reporting period/FY 2024 payment determination, to require that hospitals report one self-selected calendar quarter of data for: (a) three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs (84 FR 42503). We refer readers to section VIII.A.10.e of the preamble of this final rule where we discuss our finalized proposal to progressively increase the quarters of eCQM data, beginning with the CY 2021 reporting period/FY 2023 payment determination.

As eCQM reporting for the Hospital IQR Program continues to advance and hospitals have gained several years of experience with successfully collecting and reporting eCQM data, we believe it is important to further our policy goals of leveraging EHR-based quality measure reporting in order to incentivize data accuracy, promote interoperability, increase transparency, and reduce long-term provider burden by providing public access to the reported eCQM data. Originally, as we incorporated eCQMs into the Hospital IQR Program on a voluntary basis, we stated that we would need time to assess the data submitted by hospitals to determine the optimal timing and transition strategy for publicly reporting eCQM data (78 FR 50813). We finalized that eCQM data reported for the Hospital IQR Program would only be publicly reported if we determine the data are accurate enough to be reported (78 FR 50818). In the FY 2016 IPPS/LTCH PPS final rule when we made the reporting of eCQMs required rather than voluntary, we stated that any data submitted electronically would not be posted on the *Hospital Compare* website at that time, and that we would address public reporting in future rulemaking, after the conclusion and assessment of the validation pilot (80 FR 49698).

The eCQM validation pilot was completed in 2015 and was addressed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57174). Building upon the validation pilot, we adopted procedures to begin the required validation of eCQM data under the Hospital IQR Program in the FY 2017 IPPS/LTCH PPS final rule, and stated that the first validation of eCQM data would occur in spring 2018 to validate data from the CY 2017 reporting period. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180 through 57181), the validation process for eCQMs was established as an incremental process to ensure hospitals are able to successfully report the medical records that correspond to the data used for eCQM measure reporting. Scoring for eCQM validation is different, because the accuracy of eCQM data submitted for validation currently does not affect a hospital's payment determination.

Our validation of eCQM data submitted from CY 2017 and CY 2018 has demonstrated that hospitals are capable of reporting eCQM measure data. Since the eCQM validation pilot, we have completed eCQM data validation from the CY 2017 reporting period and the CY 2018 reporting period, and worked with stakeholders to develop a more fulsome understanding of the eCQM data submitted. Our review of the CY 2017 and CY 2018 eCQM data submitted for validation included an analysis of over 1,200 patient episodes of care submitted by over 190 hospitals per reporting period. The majority of hospitals successfully submitted validation records within the timeline requested. The results demonstrate that over half of the measures validated had agreement rates of 80 percent or better. Agreement rates are the ratios which reflect the frequency at which a hospital's electronically reported medical record data matches results adjudicated by the Clinical Data Abstraction Center (CDAC). CMS calculates an agreement rate for each hospital. Our analysis demonstrates that hospitals continue to improve the accuracy of identifying patients appropriate for measure denominator inclusion, and tend to accurately report a wide variety of data types, including diagnoses, medications, and laboratory values. Based on our review of the CY 2017 and CY 2018 eCQM data submitted for validation, and on the finding that the majority of eCQM data was reported with agreement rates of 80 percent or better, we believe eCQM data are accurate enough to be publicly reported in aggregate. Because eCQM validation examines eCQMs on a chart-by-chart basis (as opposed to in aggregate) and affects payment, in section VIII.A.10.f. of the preamble of this final rule, we discuss the finalized proposal that eCQM validation continue to be based on successful submission of at least 75 percent of the requested medical records for eCQM validation instead of reporting accuracy. In the interests of providing data to the public as quickly as possible, and as expressed in more detail later in this section, we proposed to begin public reporting of eCQM data beginning in CY 2022 using data reported for the CY 2021 reporting period/FY 2023 payment determination.

(2) Public Reporting Requirements of eCQMs for the CY 2021 Reporting Period/FY 2023 Payment Determination and Subsequent Years

Based on our validation of eCQM data submitted from CY 2017 and CY 2018, and in alignment with our goal to encourage data accuracy and transparency, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32847), we proposed to publicly report eCQM data beginning with the eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. These data could be made available to the public as early as the fall of 2022. We refer readers to section VIII.A.10.f.(2). of the preamble to this final rule for a discussion of finalized chart-abstracted measure and eCQM validation weighted scoring.

As with other Hospital IQR Program measures, hospitals would have the opportunity to review their data before they are made public, as required by section 1886(b)(3)(B)(viii)(VII) of the Act, during a 30-day preview period in accordance with previously finalized policies (76 FR 51608). Measure data, including eCQM data, are published on the *Hospital Compare* and/or *https://data.medicare.gov* websites or successor websites.

We plan to continue assessing the eCQM data submitted in future years and will continue working to ensure that hospitals receive feedback on their validation results aimed at improving transparency and reporting accuracy. We are committed to providing data to patients, consumers, and providers as quickly as possible so they are empowered to make informed decisions

about their own, and their patients' healthcare.

Understanding that it will be important for hospitals and stakeholders alike to know how to find the eCQM data once they are publicly posted, we would convey any updates to the posting locations through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet and eCQI Resource Center websites.

We also refer readers to section VIII.D. of the preamble of this final rule for a discussion of a similar proposal in the Medicare Promoting Interoperability Program. We solicited public comment on this proposal.

Comment: A few commenters supported public reporting of eCQM data for the CY 2021 reporting period/FY 2023 payment determination, with these data available to the public as early as Fall 2022. A commenter stated the proposal strikes a balance between reducing the administrative burden for providers of collecting and reporting eCQM data without sacrificing the meaningfulness of quality information available to the public and also ensuring that CMS has a more robust dataset to make payment decisions. A commenter finds the proposed change reasonable and appropriate and agrees that the current submission requirement does not effectively capture performance trends. A few commenters appreciated the greater public disclosure of eCQM data and agreed that the proposed change will provide a more accurate picture of overall performance for hospitals.

Response: We thank commenters for their support.

Comment: A few commenters requested additional information about the proposal to begin public reporting of eCQM data and publish data on the *Hospital Compare* and/or successor websites including information on benchmarking for peer comparisons, data interpretation by consumers and hospitals, expectations for timeliness for eCQM specification and vendor updates, and the source of the data that would be published. A commenter questioned if a target will be set for each measure and if hospital standing will be shown by percentile. A few commenters expressed concerns about consumers understanding the data and recommended CMS educate consumers about the differences in measurement methods for eCQM, chart-abstracted, and claims-based measures.

Response: We appreciate commenters' requests for additional information. Regarding benchmarks for peer comparisons, we remind readers that the Hospital IQR Program is a pay-for-reporting program, and therefore, there are no set performance targets. Similar to other publicly reported Hospital IQR Program measures, we plan to publish state and national rates for each eCQM that has a sufficient level of hospital reporting to reliably calculate and display. Similar to other publicly reported Hospital IQR Program measures, we plan to publish state and national rates for each eCQM that has a sufficient level of hospital reporting to reliably calculate and display. However, we do refer readers to the CY 2021 OPPS/ASC proposed rule where we are proposing a new methodology for the Overall Hospital Quality Star Ratings, which would use Hospital IQR Program measure data (85 FR 48996 through 49027). As proposed, these star ratings would use CMS quality data, including Hospital IQR Program and eCQM data, posted on the *Hospital Compare* website to assign hospitals a star rating and would provide meaningful peer comparisons on overall hospital performance through the application of peer grouping that allows hospital scores to be equivalent and comparable among all hospitals (85 FR 49022 through 49025). We encourage stakeholders to submit comments related to this methodology under that proposed rule.

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to begin publicly reporting eCQM data beginning with the eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years (85 FR 32847). These data could be made available to the public as early as the fall of 2022. We stated that measure data, including eCQM data, are published on the *Hospital Compare* and/or the *https://data.medicare.gov* website or successor websites (85 FR 32847). As a clarification, we plan to initially publish CY 2021 reporting period/FY 2023 payment determination eCQM data, of which there will be two quarters of data per our finalized policy in sectionVIII.A.9.e. of this final rule, on *https://data.medicare.gov*, or its successor website, before publishing it on the *Hospital Compare,* or its successor website, sometime in the future. The *https://data.medicare.gov* website, or its successor website, provides the public with access to downloadable datasets to ensure the information is publicly available. As more eCQM data are progressively reported, we will then additionally display the information on the *Hospital Compare* website, or its successor website, where comparisons of hospital performance will be available. We believe this gradual approach is appropriate because it advances our goal to accelerate the use of eCQMs in quality reporting while supporting providers as they gain familiarity and success with increasing eCQM submissions.

Regarding consumer and hospital interpretation of the eCQM data, we note that there are public resources available to help consumers better understand measurement methods for different types of measures used in the Hospital IQR Program, and we refer readers to general information about chart-abstracted measures on the *medicare.gov* website [469] and National Quality Forum website [470] as well as specifications and implementation guides for eCQMs are available on the eCQI Resource Center site (see *https://ecqi.healthit.gov/*). Additionally, when the eCQM data is published on the *Hospital Compare* and/or *https://data.medicare.gov* websites, or successor websites, we will post the same explanations and information that we currently post regarding other measure data to assist hospitals and consumers in understanding the data.[471] We understand the importance of publicly displaying eCQM data in a consumer-friendly format to provide meaningful information on hospital performance for patients, families, and caregivers. In addition to hosting consumer-friendly webinars,[472] we also refer readers to the Hospital IQR Program Resources and Quality Reporting Center Newsletters available on the QualityNet website.[473]

We also appreciate commenters' requests for additional information related to eCQM specifications and vendor updates. Under the Hospital IQR Program, hospitals are required to submit data on each specified measure in accordance with the measure's specifications for a particular period of time (84 FR 42501). This submitted data

[469] *Medicare.gov Hospital Compare* measures and current data collection periods. *https://www.medicare.gov/HospitalCompare/data/Data-Updated.html#MG3.*

[470] National Quality Forum, hospital inpatient quality measures. *http://www.qualityforum.org/Home.aspx.*

[471] Hospital Compare Data Resource. *https://www.medicare.gov/hospitalcompare/Data/Data-Updated.html#%20.*

[472] Hospital IQR Program 2020 Webinars & Calls, available at: *https://www.qualitynet.org/inpatient/iqr/webinars.*

[473] Hospital IQR Program Resources, available at: *https://www.qualitynet.org/inpatient/iqr/resources#tab1* and Quality Reporting Center Newsletters, available at: *https://www.qualitynet.org/inpatient/iqr/resources#tab3.*

will be the source of the publicly reported eCQM data. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.qualitynet.org.* The technical specifications used for electronic clinical quality measures (eCQMs) are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). We generally update the measure specifications on an annual basis through the Annual Update, which includes code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/.* For example, for the CY 2019 reporting period/FY 2021 payment determination, hospitals needed to submit eCQM data using the May 2018 Annual Update and any applicable addenda. We refer readers to the FY 2020 IPPS/LTCH PPS final rule for the most recent statement of the sub-regulatory process for eCQM specification updates (84 FR 42501).

Comment: Many commenters did not support public reporting of eCQM data due to concerns about eCQM data accuracy, generally. A commenter expressed concern that reporting less than 12 months of data at a time will not accurately reflect a hospital's performance. Another commenter expressed concern that the proposal to report data for a few selected eCQMs could result in publicly reported hospital performance based on as few as 12 cases.

Response: We have previously stated that eCQM data reported for the Hospital IQR Program would only be publicly reported if we determined the data are accurate enough to be reported (78 FR 50818). We refer readers to section VIII.A.9.e. of this final rule where this analysis is discussed in more detail. Based on our review of data submitted for CY 2017 and CY 2018 validation, we believe eCQM data is accurate enough to publicly report, with the majority of eCQM data with agreement rates of 80 percent or better. Our review is based upon an analysis of over 1,200 patient episodes of care submitted by over 190 hospitals per reporting period (85 FR 32846). As stated previously, we believe that public reporting of eCQM data will incentivize data accuracy and increase transparency. Additionally, in conjunction with this policy to publicly report eCQM data, in section VIII.A.9.e. of the preamble of this final rule, we have finalized a policy to progressively increase the number of quarters for which hospitals are required to report eCQM data. We believe that beginning to publicly report eCQM data as early as the fall of 2022, while progressively increasing the quarters of reported eCQM data, strikes the appropriate balance between the importance of public reporting eCQM data and stakeholder concerns regarding the burden associated with increasing the reporting of such data. We refer readers to section VIII.a.9.E. of this final rule, where we are finalizing a gradual approach to increasing the amount of eCQM data required. Taking that into account, for the CY 2021 reporting period/FY 2023 payment determination, we will publicly report two quarters of data. For the CY 2022 reporting period/FY 2024 payment determination, we will publicly report three quarters of data, and for the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we will publicly report four quarters of eCQM data. The following table summarizes our finalized policy:

eCQM Data Public Reporting Requirements	
Reporting Period / Payment Determination	eCQM Data Publicly Reported
CY 2021 / FY 2023	Two Quarters of Data
CY 2022 / FY 2024	Three Quarters of Data
CY 2024 / FY 2025	Four Quarters of Data

In addition, in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably determine how well the hospital is performing.

Comment: Some commenters did not support public reporting of eCQM data due to concerns about eCQMs being compared to similar chart-abstracted measures.

Response: As noted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42502), following the removal of several chart-abstracted clinical process of care measures in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41562 through 41567), the only chart-abstracted measure for which there was also an eCQM version was PC–01. The eCQM version of the PC–01 measure was removed from the Hospital IQR Program in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41569). Therefore, there are no longer any eCQMs that have similar chart-abstracted measures.

Comment: A few commenters did not support public reporting of eCQM data from the CY 2021 reporting period/FY 2023 payment determination data beginning as early as Fall 2022 due to the impact of the COVID–19 PHE on hospitals, including needing to reassign and reduce hospital staff, redirect resources, and concerns about increasing provider burden. A few commenters did not support our proposal to publicly report eCQM data due to concern about measure performance during the COVID–19 PHE. Several commenters opposed publishing data on *Hospital Compare* for the CY 2021 reporting period and recommended a delay until the CY 2022 reporting period or later due to the COVID–19 PHE that may impact the validity and reliability of data, especially when comparing performance across hospitals. A few commenters supported the proposal to publicly report eCQM data but recommended that CMS confer with hospitals to ensure data reporting for the CY 2021 reporting period will not impose unreasonable administrative burden during the COVID–19 PHE.

Response: We continue to closely monitor and analyze the impact that the unpredictable nature of the COVID–19 PHE may have on the national comparability of Hospital IQR Program measures as well as burden on hospitals. We will continue to communicate as needed through routine communication channels and to Medicare beneficiaries. We appreciate the commenters' concerns regarding the impact COVID–19 PHE has had on hospitals and have issued exceptions

related to the COVID–19 PHE in an effort to reduce burden, provide flexibility to hospitals, and help hospitals maximize their capacity to focus on patient care. Additionally, under the Hospital IQR Program ECE Policy, hospitals may request an exception if they are unable to fulfill program requirements due to extraordinary circumstances not within their control. The ECE policy includes requests related to the submission of eCQM data if a hospital experiences a hardship that prevents it from eCQM reporting (80 FR 49695). We refer readers to section VIII.A.14. for additional information. However, we do not believe that public reporting of reported eCQM data adds to that burden because public reporting will not change how hospitals submit or report their eCQM data nor the number of measures that will be required to be reported. We also note that the CY 2020 reporting period/FY 2022 payment determination data will not be publicly reported, as we are finalizing our proposal to start public reporting of eCQM data with the CY 2021 reporting period/FY 2023 payment determination. Regarding opposition to publishing eCQM data on *Hospital Compare* for the CY 2021 reporting period/FY 2023 payment determination and a recommendation to delay publishing eCQM data until the CY 2022 reporting period/FY2024 payment determination, our plan is to initially publish CY 2021 eCQM data on *https://data.medicare.gov*, or its successor website, before publishing the data on *Hospital Compare,* or its successor website, sometime in the future. We will continue to communicate as needed through routine communication channels and to Medicare beneficiaries.

Comment: Some commenters did not support public reporting of eCQM data due to the burden for some hospitals to successfully submit eCQM data.

Response: We understand commenters' concern. However, we believe we have sufficiently mitigated potential burden for hospitals by taking an incremental approach to allow hospitals to become familiar with eCQM reporting (see section VIII.A.9.e. in the preamble of this final rule for a discussion of our incremental approach). After a period of voluntary submission, which began in the CY 2014 reporting period/FY 2016 payment determination (78 FR 50818), hospitals have had several years of consistent eCQM measure submission requirements (82 FR 38361, 83 FR 41604, 84 FR 42502). Internal reviews of Hospital IQR Program eCQM submission data revealed that 97 percent of eligible hospitals successfully submitted one quarter of eCQM data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination (84 FR 42458). Additionally, we provide numerous resources to support successful eCQM data reporting[474] and host events and webinars to enhance understanding of eCQM reporting.[475]

Comment: Many commenters did not support public reporting of eCQM data as early as Fall 2022 and recommended a delay in public reporting to provide hospitals with additional time to prepare, to provide greater technical consistency, or until four quarters of data are required to be reported.

Response: We appreciate the commenters' feedback but disagree that hospitals need more time to prepare for public reporting of eCQM data. As noted previously, CY 2021 will be the fifth year that hospitals have submitted eCQM data and validation of CY 2017 and CY 2018 data has shown that a majority of eCQM data was reported with agreement rates of 80 percent or higher. We have therefore determined that eCQM data is accurate enough to begin reporting. We interpret the phrase ''greater technical consistency'' to refer to consistency in eCQM specification implementation in EHRs, consistency in the extraction of structured data for eCQM measure calculation, and consistency in testing to identify eCQM accuracy. We understand the references to be aspects of eCQM reporting and validation. In VIII.A.9.b., we reference the technical specifications for quality measures and refer readers to the FY 2019 IPPS/LTCH PPS final rule where we summarize how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications. We did not propose any changes to these policies. As described in section VIII.A.10. of this final rule, we are continuously working to improve eCQM validation and finalized several changes to that process. We believe the eCQM educational review process policy finalized in section in VIII.A.10.h.(2) of this final rule will support hospitals in better understanding the processes and data for eCQM validation.

Additionally, although we appreciate commenters' concern about public reporting eCQM data representing fewer than four quarters of data, we disagree that this should inhibit the advancement of public reporting of eCQM data. As stated previously, we believe it is important to provide data to the public as soon as practicable while increasing the amount of eCQM data to be reported to CMS. We believe that beginning to publicly report eCQM data as early as the fall of 2022, while progressively increasing the quarters of reported eCQM data strikes the appropriate balance between the importance of transparency by publicly reporting eCQM data and stakeholder concerns about using sufficient data for publicly reporting eCQM data.

Comment: Many commenters did not support public reporting of eCQM data beginning as early as Fall 2022, citing concern that inconsistency in the number of cases reported and the self-selection of eCQMs reported across individual hospitals might not accurately depict hospital performance. These commenters recommended aligning the start of public reporting with one consistent mandated eCQM across all hospitals.

Response: We refer readers to the FY 2020 IPPS/LTCH PPS final rule, where we previously finalized mandatory reporting of the Safe Use eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination (84 FR 42503 through 42505). Therefore, beginning with public reporting in fall of 2023, there will be one eCQM that all Hospital IQR Program hospitals must submit, in addition to the other eCQMs they may self-select. We believe we should begin public reporting prior to that time (that is, fall 2022 as proposed), because our finalized public reporting policy advances our step-wise approach to achieve the goal of increased use of eCQMs in quality reporting while supporting providers as they gain familiarity and success with increasing eCQM submissions. We acknowledge the commenters' concern, and as detailed in section VIII.A.9.e. of the preamble of this final rule, we are finalizing incremental increases in eCQM data reporting requirements over a 3-year period. As we described previously, we plan to initially publish CY 2021 eCQM data, of which there will be two quarters of data per our finalized policy in sectionVIII.A.9.e. of this final rule, on *https://data.medicare.gov*, or its successor website, before publishing it on *Hospital Compare,* or its successor website, sometime in the future. The *https://data.medicare.gov* website, or its successor website, provides the public with access to downloadable datasets to ensure the information is publicly

[474] eCQI Resource Center, Tools and Resources. *https://ecqi.healthit.gov/ecqi-tools-key-resources*; eCQI Resource Center Measure Collaboration (MC) Workspace. *https://ecqi.healthit.gov/mc-workspace-2.*

[475] Upcoming events and webinars, eCQI Resource Center. *https://ecqi.healthit.gov.*

available. As more eCQM data are progressively reported, we will then additionally display the information on the *Hospital Compare* website, or its successor website, where comparisons of hospital performance will be available. We believe these finalized policies address the commenters' concerns while providing flexibility for hospitals and their vendors to build upon and utilize investments in their EHRs.

Comment: Many commenters did not support public reporting of eCQM data beginning as early as Fall 2022 due to a lack of insight on hospital performance individually or in comparison with other hospitals, and lack of analyses from prior eCQM validation efforts to provide useful feedback. A commenter noted that some hospitals have participated in eCQM audits but have not received audit results nor reports that compare an audited hospital to all reporting organizations.

Response: We thank commenters for their feedback. As with other Hospital IQR Program measures, hospitals will have the opportunity to review their eCQM data before they are made public, as required by section 1886(b)(3)(B)(viii)(VII) of the Act, during a 30-day preview period in accordance with finalized policies (76 FR 51609). Hospitals will be able to obtain feedback on their individual performance from their EHR vendors and through feedback reports provided to them from the HQR system, which contain information on file history, data accuracy, and measure outcomes.[476] Further, as noted previously, publicly reporting eCQM data on *https://data.medicare.gov* will provide hospitals with the opportunity to make comparisons to their peers before the information begins to also be publicly displayed on the *Hospital Compare* website, or its successor website. Additionally, we refer readers to the CY 2021 OPPS/ASC proposed rule where we are proposing a new methodology for the Overall Hospital Quality Star Ratings, which would use Hospital IQR Program measure data, among other CMS quality data, to summarize hospital quality measure results and provide meaningful insight on hospital performance by assigning acute care hospitals and facilities that provide acute inpatient and outpatient care in the U.S. with an overall rating between one and five whole stars (85 FR 48996 through 49027).

We interpret the commenters' inquiry about ''eCQM audits'' to refer to eCQM validation. We refer readers to section VIII.A.10.h. of the preamble of this final rule, where we finalized an education review process for validated eCQM data beginning with validation affecting the FY 2023 payment determination and subsequent years, which will provide hospitals with additional analyses of eCQM validation.

Comment: Several commenters did not support our proposal to publicly report eCQM data for the CY 2021 reporting period and asked for CMS to provide hospitals the opportunity to review the data. These commenters recommended a dry run with one quarter and two quarters of data to enable hospitals to preview their performance and national comparison data confidentially before the data are made public. Commenters recommended CMS conduct reliability analyses to determine the minimum volume of cases needed for public reporting and make the analyses public. Commenters also recommended that CMS provide clear information about how data will be presented to the public and provide information on the process to dispute publicly accessible data.

Response: We thank the commenter for the comments. As stated previously, the publicly reported eCQM data will first be reported on the *https://data.medicare.gov* website, or its successor website, which provides the public with access to downloadable datasets. As more eCQM data are progressively reported, we will then additionally display the information on the *Hospital Compare* website, or its successor website.

We interpret the term ''dry run'' to reference the dry run provision in the Blueprint for the CMS Measures Management System, utilized during the first use of a measure in a CMS program or first results reporting.[477] We do not believe a dry run before the start of public reporting is necessary and have determined that the eCQM data are accurate enough to begin reporting. As noted previously, the CY 2021 reporting period/FY 2023 payment determination will be the fifth year that hospitals have submitted eCQM data and for each year, we have provided confidential feedback reports on the eCQM data file submissions to each individual hospital.[478] Internal review of eCQM submission data revealed that 97 percent of eligible hospitals successfully submitted one quarter of eCQM data for four self-selected eCQMs for the CY 2018 reporting period/FY2020 payment determination (84 FR 42458). We refer readers to section VIII.A.9.e. of this final rule where this analysis is discussed in more detail. In addition, as previously stated, as with other Hospital IQR Program measures, hospitals would have the opportunity to preview their eCQM data before they are made public, as required by section 1886(b)(3)(B)(viii)(VII) of the Act, during a 30-day preview period in accordance with previously finalized policies (76 FR 51608). Additionally, we refer readers to the CY 2021 OPPS/ASC proposed rule where we are proposing a new methodology for the Overall Hospital Quality Star Ratings, which would use Hospital IQR Program measure data (85 FR 48996 through 49027). As proposed, these star ratings would use CMS quality data, including Hospital IQR Program and eCQM data, posted on the *Hospital Compare* website to assign hospitals a star rating and would provide meaningful peer comparisons on overall hospital performance through the application of peer grouping that allows hospital scores to be equivalent and comparable among all hospitals (85 FR 49022 through 49025). We encourage stakeholders to submit comments related to this methodology under that proposed rule.

We thank commenters for their recommendation to conduct measure reliability analyses to determine the minimum number of cases needed for public reporting. Validation of CY 2017 reporting period/FY 2019 payment determination data and CY 2018 reporting period/FY 2020 payment determination data has shown that a majority of eCQM data was reported with agreement rates of 80 percent or higher. Our review is based upon an analysis of over 1,200 patient episodes of care submitted by over 190 hospitals per reporting period (85 FR 32846). We refer readers to section VIII.A.10. of this final rule where this is discussed in more detail. We note that in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably

[476] CMS Hospital Quality Reporting System Now Accepting CY 2019 eCQM Data, available at: *https://ecqi.healthit.gov/cms-hospital-quality-reporting-system-now-accepting-cy-2019-ecqm-data.*

[477] Blueprint for CMS Measures Management System, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[478] *https://www.qualityreportingcenter.com/globalassets/iqr_resources/030819/cy-2019-ecqm-ehr-reports-overview_vfinal508.pdf.*

determine how well the hospital is performing.

Generally speaking, measure data, including eCQM data, are published on the *Hospital Compare* and/or *https://data.medicare.gov* websites or successor websites. As discussed above, we are clarifying that we plan to initially publish CY 2021 reporting period/FY 2023 payment determination eCQM data, of which there will be two quarters of data per our finalized policy in sectionVIII.A.9.e. of this final rule, on *https://data.medicare.gov*, or its successor website, before publishing it on *Hospital Compare,* or its successor website, sometime in the future. The *https://data.medicare.gov* website, or its successor website, provides the public with access to downloadable datasets to ensure the information is publicly available. As more eCQM data are progressively reported, we will then additionally display the information on the *Hospital Compare* website, or its successor website.

Comment: Several commenters opposed publishing eCQM data on *Hospital Compare* citing concerns about data context as it pertains to safety net hospitals.

Response: We thank commenters for their feedback concerning the public reporting of eCQM data as it pertains to safety net hospitals. We plan to monitor the initiation of public reporting of eCQM data and welcome continued feedback from all stakeholders through webinars, listservs, and help desk questions as information shared can be used to inform public reporting processes over time. We will continue to monitor trends in performance, including that of safety net hospitals. Additionally, we refer readers to the CY 2021 OPPS/ASC proposed rule, where we are proposing a new methodology for the Overall Hospital Quality Star Ratings, which would use Hospital IQR Program measure data (85 FR 48996 through 49027). As proposed, these star ratings would use CMS quality data, including Hospital IQR Program and eCQM data, posted on the *Hospital Compare* website to assign hospitals a star rating. This would provide meaningful peer comparisons on overall hospital performance through the application of peer grouping that allows hospital scores to be equivalent and comparable among all hospitals (85 FR 49022 through 49025). We encourage stakeholders to submit comments related to this methodology under that proposed rule.

After consideration of the public comments, we are finalizing our proposal as proposed to publicly report eCQM data beginning with eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. As a clarification, we plan to initially publish CY 2021 reporting period/FY 2023 payment determination eCQM data, of which there will be two quarters of data per our finalized policy in section VIII.A.9.e. of this final rule, on *https://data.medicare.gov*, or its successor website, before publishing it on the *Hospital Compare* website, or its successor website, sometime in the future. We also refer readers to section VIII.D.6.c. of this final rule where we are also finalizing similar polices under the PI Program.

c. Overall Hospital Quality Star Rating

As mentioned above, in the CY 2021 OPPS/ASC proposed rule, we proposed a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating) (85 FR 48996 through 49027). The Overall Star Rating would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on *Hospital Compare* or its successor site through CMS quality programs, including data from the Hospital IQR Program. We refer readers to section XVI. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of that proposed rule for details.

13. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We did not propose any changes to this policy.

14. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *http://www.QualityNet.org/* for our current requirements for submission of a request for an exception. We did not propose any changes to this policy.

B. Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt-Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act, and it applies to hospitals described in section 1866(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). Under the PCHQR Program, PCHs must submit to the Secretary data on quality measures with respect to a program year in a form and manner, and at a time, specified by the Secretary.

For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624); CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154); and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524).

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to incorporate refinements to two existing measures in the PCHQR Program measure set—the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139). While we did not propose to add any new measures or remove any existing measures, we continue to assess the PCHQR Program measure set's alignment with the Meaningful Measures Initiative, which is discussed in more detail in I.A.2. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148).

2. Summary of PCHQR Program Measures for the FY 2023 Program Year

The table in this section of this rule summarizes the PCHQR Program measure set for the FY 2023 program year.

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FY 2023 PCHQR Program Measure Set

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
N/A	0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS*	0166	HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer

***Note:** In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524), we finalized our proposal to remove the "pain management questions" from the HCAHPS survey beginning with October 2019 discharges.

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3. Refinements to the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) Beginning With the FY 2023 Program Year

a. Background

In the FY 2021 IPPS/LTCH PPS proposed rule, we provided an overview of the history of CAUTI and CLABSI measures in the PCHQR Program (85 FR 32848 through 32849). Specifically, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53559), we adopted the Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138) and Central line-associated Bloodstream Infection (CLABSI) (NQF #0139) measures for use in the PCHQR Program beginning with the FY 2014 program year, and we refer readers to this rule for a detailed discussion of these measures. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503), we proposed to remove both measures from the program because we believed that removing the measures would reduce program costs and complexities associated with the use of these data by patients in decision-making. We stated that we believed the costs, coupled with the high technical and administrative burden on PCHs associated with collecting and reporting the measure data, outweighed the benefits of their

continued use. We further stated that it had become difficult for CMS to publicly report data on these measures due to the low volume of data produced and reported by the small number of PCHs that participate in the PCHQR Program, and that we lacked an appropriate methodology to publicly report these data. For these reasons, we believed that the measures should be removed beginning with the FY 2021 program year under measure removal Factor 8: The costs associated with the measures outweighed the benefit of their continued use in the program.

However, after considering the comments we had received on this proposal and other updated information, in the CY 2019 OPPS/ASC final rule (83 FR 59150), we decided to retain both the CAUTI and CLABSI measures in the PCHQR Program. We stated that since the time we made our proposal, we had conducted our own analyses regarding the continued use of the CAUTI and CLABSI measures using updated CDC data. We also stated that although the CDC had previously believed that oncology unit locations, including those in PCHs, had a higher incidence of infections than other types of units in acute care hospitals, the CDC now believes, after controlling for location type, that oncology unit locations in PCHs do not have a higher incidence of infection than oncology units within other acute care hospitals. We stated that the CDC's updated analysis also produced a consistent finding that cancer hospital status was not a significant risk factor in any of the device-associated HAI risk models, including those used for CAUTI and CLABSI. Lastly, we stated that we believe these results indicate that reporting PCH CAUTI and CLABSI performance measure data is just as important as reporting acute care hospital CAUTI and CLABSI performance measure data (83 FR 59151). Based on this updated information, as well as the public comments, we concluded that the importance of emphasizing patient safety in quality care delivery justified retaining the CAUTI and CLABSI measures in the PCHQR Program (83 FR 59151).

We also noted in the CY 2019 OPPS/ASC PPS final rule that the CAUTI and CLABSI measure specifications had been recently updated to use new standard infection ratio (SIR) calculations that can be applied to cancer hospitals, including PCHs. We noted that this updated SIR calculation methodology is different than the methodology we are currently using to calculate the CAUTI and CLABSI measures. Additionally, the use of raw location-stratified rates in the current methodology had created a concern that the CAUTI and CLABSI data calculated under the current methodology might appear to inaccurately show lower performance among PCHs than the performance reported by acute care hospitals that are reporting CAUTI and CLABSI data using the updated methodology (83 FR 59151). We stated that we believed the updated methodology addresses this concern because the updates include rates that are stratified by patient care locations within PCHs, without the use of predictive models or comparisons in the rate calculations. We also stated that we intended to propose to adopt these updated versions of the CAUTI and CLABSI measures, and that we would work closely with the CDC to assess the updated risk adjusted versions of these measures (83 FR 59151).

b. Updates to the CAUTI and CLABSI Measures

In the FY 2021 IPPS/LTCH PPS proposed rule, we discussed our proposal to refine the CAUTI and CLABSI measures by adopting the updated SIR calculation methodology. This updated methodology was developed by the CDC and calculates rates that are stratified by patient care locations within PCHs, without the use of predictive models or comparisons in the rate calculations (85 FR 32849 through 32850).

(1) Description of the CDC Re-Baselining Efforts

The CDC's National Healthcare Safety Network (NHSN) uses healthcare-associated infection (HAI) incidence data from a prior time period and a standard population of facilities that report data to the NHSN (such as all healthcare facilities of a specified type) to establish a HAI baseline for those facilities, including a HAI baseline for CAUTI and CLABSI.[479] The NHSN then uses that baseline to calculate the SIR. For both of these measures, the SIR is calculated as a comparison of the actual number of HAIs reported by a facility with the number that would be predicted by the HAI baseline.[480]

In 2016, the CDC used 2015 HAI incidence data to update both the source of aggregate data and the risk adjustment methodology used to create the HAI baselines. As a result, the CDC established new HAI baselines for purposes of calculating the SIRs used to calculate HAI measures, including the CAUTI and CLABSI measures.[481] The CDC's decision to use 2015 data was multifactorial and relied partially on its implementation of updated surveillance protocols and definitions as well as increased reporting of certain HAI types by additional healthcare facility types.[482]

During its re-baselining effort, the CDC determined that it could generate HAI baselines that produce more accurate SIR calculations for the 17 hospitals that enroll in NHSN as facility type ''HOSP–ONC'' (11 PCHs and 6 other hospitals that classify themselves as cancer hospitals but are not PCHs for purposes of Medicare) by standardizing the new HAI baselines across infection type and facility type.[483] Therefore, the CDC created a risk adjustment model for acute care hospitals and determined that it could include the 17 cancer hospitals in that risk adjustment model because it found that cancer hospital status was not a significant risk factor that would preclude their inclusion.[484]

The CDC also evaluated what additional oncology-specific patient locations (for example, hematology/oncology ward, medical oncology ICU) should be adjusted for when deriving SIR calculations for hospitals in the acute care risk adjustment model. The CDC considered this because examining patient care location allows for the assessment of which patient populations are at higher risk for CAUTI and CLABSI incidences. Further, stakeholders had previously raised concerns that the omission of a risk adjustment for oncology-specific patient care locations in the SIR calculations could inaccurately appear to show lower performance (that is, higher SIR) on the HAI measures, including CLABSI and CAUTI, by PCHs and other cancer hospitals than other acute care hospitals; adjusting for oncology-specific patient locations as a part of the new risk model mitigates this concern. When the CDC stratified by location within the acute care hospital risk adjustment model, it found that in comparison to non-oncology-specific patient locations, the oncology-specific locations, particularly those designated as oncology units,[485] produced statistically significant differences in HAI measure performance. As a result, the CDC further updated the acute care

[479] Centers for Disease Control and Prevention. ''Paving Path Forward: 2015 Rebase line.'' Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

[480] Ibid.

[481] *Ibid.*

[482] Summary of CDC's Rebaseline Analysis of NHSN HAI Data. Updated September 7, 2018.

[483] Ibid.

[484] Ibid.

[485] A ward is a floor or section of a hospital or outpatient clinic where cancer patients are treated.

risk adjustment model to stratify the HAI baselines by oncology-specific location types.[486]

(2) CAUTI and CLABSI Results Using the Updated HAI Baselines That Incorporate New Risk-Adjustment

We indicated in the FY 2021 IPPS/LTCH PPS proposed rule that the CDC tested the CAUTI and CLABSI measures based on the updated HAI baselines that incorporate the new risk adjustment described above (85 FR 32850). According to the CDC's calculation methodology, when assessing the performance results for the CAUTI or CLABSI measure, a p-value of 0.05 or less was noted to be statistically significant.[487] They noted that when assessed based on the adjustment for oncology unit, both the CAUTI and CLABSI measures yielded p-values of <0.0001.[488] This means that within the acute care hospital risk adjustment model, the categorization of a patient care location as an oncology unit is a statistically significant predictor of CAUTI and CLABSI incidence. Given that the majority of reporting locations within PCHs would be classified as oncology units, the application of this additional risk adjustment by location within the acute care hospital risk adjustment model will result in a more accurate assessment of the incidence of CAUTIs and CLABSIs within PCHs.

(3) Measure Applications Partnership Analysis of the Refinements to the CAUTI and CLABSI Measures

In compliance with section 1890A(a)(2) of the Act, we included the updated versions of the CAUTI and CLABSI outcome measures in a publicly available document entitled ''2019 Measures Under Consideration Spreadsheet.'' [489] This is a list of quality and efficiency measures under consideration for use in various Medicare programs, which the Measure Applications Partnership (MAP) reviews. The MAP supported the use of both refined measures in the PCHQR Program for rulemaking.[490]

Regarding the CAUTI measure, the MAP indicated that because CAUTIs are the most common HAI, hospitals should continue working to reducing their incidence and prevalence across all inpatient settings. The MAP also determined that even though CAUTI is a chart-abstracted measure that is burdensome to collect, the benefit of collecting data on this measure outweighs that cost.[491] In addition, the MAP acknowledged it is imperative to evaluate CAUTI incidence in all inpatient settings, including cancer hospitals. The revised version of this measure was endorsed by the National Quality Forum on October 23, 2019.[492] We refer readers to NQF's Final Report—Spring 2019 Cycle [493] for a more detailed discussion of this measure.

For the CLABSI measure, the MAP also determined that even though the measure is chart-abstracted and burdensome to collect, the benefit of collecting data on this measure outweighs the cost.[494] The MAP further noted that this measure is pertinent in the healthcare domain of patient safety and suggested that the CDC consider the differences in types of cancer and/or differences in types of cancer treatments when assessing the measure's performance in the future.[495] Like the CAUTI measure, we note that the revised version of this measure was endorsed by the NQF on October 23, 2019.[496] We refer readers to NQF's Final Report—Spring 2019 Cycle [497] for a more detailed discussion of this measure.

c. Summary of Proposal

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to refine the CAUTI and CLABSI measures by adopting the updated measure specifications that use the new SIR calculation methodology, which calculates measure rates that are stratified by patient care locations (specifically, oncology units) within PCHs (85 FR 32850). We indicated that we believe it is important to continue to measure CAUTI and CLABSI incidence because of the implications these two measures have in the patient safety domain of healthcare. We also believe it is important to provide stratified performance results where appropriate for the cohort of patients with cancer, which is why we believe that applying the CDC's update of the risk-adjustment model (which will ultimately yield more precise SIR results) is appropriate for the CAUTI and CLABSI measures. Implementation of the refined, stratified measures will make the measures more representative of the quality of care provided at PCHs, particularly when performance rates are compared to other acute care hospitals. Further, stratified performance results will more accurately demonstrate the incidence of CAUTI and CLABSI for comparison among PCHs. In addition, implementation of the refined versions would address previous stakeholder requests to use a statistically significant method for public reporting of these measures. Lastly, implementing the refined versions of these measures means that the PCHQR Program would be utilizing the most recently NQF-endorsed versions of these measures.

We invited public comment on our proposal to refine the Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138) and Central line-associated Bloodstream Infection (CLABSI) (NQF #0139) measures to utilize the updated HAI baselines that incorporate an updated risk adjustment approach, as developed by the CDC, for the FY 2023 program year and subsequent years.

Comment: Several commenters supported the proposed refinements to the CAUTI and CLABSI measures. Commenters expressed that reporting CAUTI and CLABSI performance data for PCHs remains no less important than reporting acute care hospital CAUTI and CLABSI data. Commenters also noted that avoiding HAIs is an appropriate goal across all hospitals, especially PCHs where safety concerns for patients with cancer and related conditions may be heightened.

Response: We thank the commenters for their support.

Comment: Several commenters encouraged CMS to consider future refinements for these measures. While the refined measures have some level of adjustment for oncology units, commenters stated that the adjustments are not detailed enough to account for patients who suffer from significantly complex, high risk cancers. Further, while Standardized Infection Ratios (SIRs) and Adjusted Ranking Metrics (ARMs) are among the best benchmarking tools available, commenters requested that CMS base

[486] Summary of CDC's Rebaseline Analysis of NHSN HAI Data. Updated September 7, 2018.

[487] NHSN's Guide to the SIR-Updated March 2019. Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html*.

[488] Ibid.

[489] 2019 Measures Under Consideration. Information available at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[490] 2020 Considerations for Implementing Measures Draft Report—Hospitals. Available at: *http://www.qualityforum.org/map/*.

[491] Ibid.

[492] Memo CSAC Meeting—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

[493] Final Report—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

[494] 2020 Considerations for Implementing Measures Draft Report—Hospitals. Available at: *http://www.qualityforum.org/map/*.

[495] Ibid.

[496] Memo CSAC Meeting—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

[497] Final Report—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

SIRs and ARMs solely on cancer hospitals with inpatient units. If the calculation of SIRs and ARMs includes all acute care hospitals, commenters asked that CMS report these scores by individual NHSN locations to maximize interpretability and utility for quality improvement purposes. Commenters also cautioned against reporting comparisons between the cancer hospitals and all acute care hospitals. Specifically, commenters indicated that cancer hospital patient populations have a greater propensity to be immunocompromised and, consequently, comparisons between other types of hospitals and cancer hospitals would not be appropriate as rates in cancer hospitals would generally trend higher. Lastly, commenters indicated that not all PPS-Exempt and other cancer hospitals are homogenous in their services, patient populations, and case mixes. They stated that some hospitals may not generate enough data to report on a quarterly basis and that a more granular presentation of data, such as comparing similar units across hospitals, may enhance insights for consumers.

Response: We thank the commenters for their feedback. Regarding the concern about the refinements to the measures being insufficient to account for complex, high risk forms of cancer, we believe that the updated measure specifications that use the new SIR calculation methodology will allow for a more representative comparison of performance of the CAUTI and CLABSI measures in PCH settings. We will remain vigilant of data trends and continue to work cooperatively with the CDC to monitor whether or not additional refinements are warranted after an evaluation of a years' worth of performance data. We will pay particular attention to PCHs' ability to collect and report sufficient data, as we are cognizant of the issues commenters raised around generating enough data for quarterly reporting. We want to clarify that for the refined versions of the CAUTI and CLABSI measures, we only intend to calculate Standardized Infection Ratios (SIRs) and not Adjusted Ranking Metrics (ARMs) as commenters mentioned. As such, pertaining to the inclusion of acute care hospitals scores in the calculation of SIR rates, for the PCHQR Program, we intend to calculate and report PCH scores. Further, to the point of level of granularity of data for PCHs, we intend to report hospital-level SIRs that are calculated using a risk model that is applied at the individual location level (that is, oncology units). Lastly, we recognize the importance of comparability among PCHs (for example comparison of oncology units). Likewise, we will publicly report data that reflects the performance of the PCHQR Program participants. That stated, while we currently do not display comparative data of PCHs to acute care facilities for any of the measures in the PCHQR Program's measure set, we continue to believe the ability to compare data across hospitals is important for those who wish to examine general performance trends for the CAUTI and CLABSI measures.

Comment: A commenter expressed concern that the updated risk-adjustment model does not account for the impact of COVID–19. The commenter agreed that stratifying data by patient care location would yield a more statistically significant predictor of CAUTIs and CLABSIs. However, the commenter asserted that this stratification would not take into consideration COVID–19 surge conditions. Specifically, increased demand on emergency departments (EDs) and intensive care units (ICUs) have required hospitals—especially those located in COVID–19 ''hotspots''—to transfer patients to other departments or units within the hospital. The commenter also noted that COVID–19 contributed to an increase in CLABSIs in acute care facilities, due in large part to a surge in hospital capacity, with most infections occurring among patients diagnosed with COVID–19. As such, the commenter shared concern that the increase in CLABSIs may impose a greater burden on hospitals located in hotspots.

Response: We appreciate the commenter's feedback. We note that the updated risk model adjusts for several risk factors that have been found to be significantly associated with differences in infection incidence. Additionally, the CDC is collecting an optional data element regarding a patient's concurrent COVID–19 infection. While this data element is not included in the updated risk model, it can be utilized to indicate confirmed COVID–19 infection for patients with HAIs. Data reported for this element will enable a better understanding of the possible association between COVID–19 and HAIs. That stated, it is also important to note that COVID–19 status is not available for every hospitalized patient with a CAUTI or CLABSI incident, which will limit analysis opportunities, therefore determination of associated risk may not be possible. Regarding increased demand on hospital units and potential reporting burden surge for hospitals in hot spots, we note that we will not require hospitals to begin data collection for the refined CAUTI and CLABSI measures until CY 2021. Recognizing the potential for COVID–19 to impact data collection in CY 2021, we will closely monitor the reporting capacity of participating PCHs and if COVID–19 poses issues.

After consideration of the public comments received, we are finalizing our proposal to refine the Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138) and Central line-associated Bloodstream Infection (CLABSI) (NQF #0139) measures to utilize the updated HAI baselines that incorporate an updated risk adjustment approach, as developed by the CDC, for the FY 2023 program year and subsequent years.

4. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at *https://www.qualitynet.org/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We did not propose any changes to our processes for maintaining technical specifications for PCHQR Program measures.

5. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are going to be made public with respect to that PCH, prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS website.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized that although we would continue to use rulemaking to establish what year we would first publicly report data on each measure, we would publish the data as soon as feasible during that year. We also stated that our intent is to make the data available on at least a yearly basis, and that the time period for PCHs to review their data before the data are made public would

be approximately 30 days in length. We announce the exact data review and public reporting timeframes on a CMS website and/or on our applicable listservs.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42520 through 42523), we finalized that we would begin to publicly display data on a number of PCH measures as soon as is practicable due to planned website improvements that we stated could delay our ability to begin the public display. In October 2019, we began to publicly report data on the following four HAI measures: (1) Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753); (2) NHSN Facility-wide Inpatient Hospital-onset Methicillin resistant Staphylococcus aureus Bacteremia Outcome Measure (NQF #1716); (3) NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717); and (4) NHSN Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

In the table that follows, we summarize our current public display requirements for the PCHQR Program measures. The PCHQR measures' performance data is made publicly available on the Hospital Compare website or its successor. *https://www.medicare.gov/hospitalcompare/cancer-measures.html.*

Finalized Public Display Requirements for PCHQR Program

Summary of Finalized Public Display Requirements	
Measures	**Public Reporting**
● HCAHPS (NQF #0166)● Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)	2016 and subsequent years
● External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822)*	2017 and subsequent years
● American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) ● National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) ● National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) ● National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	2019 and subsequent years
● Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy**	April 2020 and subsequent years
● CAUTI (NQF #0138) ● CLABSI (NQF #0139)	Deferred until CY 2022

**Measure finalized for removal, beginning with the FY 2022 program year.*

*** Since we issued the FY 2021 IPPS/LTCH PPS Proposed Rule, we have begun to publicly display data on this measure.*

b. Public Display of the Refined Versions of the CAUTI and CLABSI Measures

As described in section VIII.B.3.b. of the preamble of the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to adopt refined versions of the CAUTI and CLABSI measures in the PCQHR Program beginning with the FY 2023 program year (85 FR 32851). We also proposed that we would begin publicly reporting the refined versions of the CAUTI and CLABSI measures in the fall of 2022 and that we would not publicly report the current versions of those measures because, as described above, the refined versions of the measures more accurately capture the quality of care furnished at PCHs (85 FR 32851).

We invited public comment on these proposals.

Comment: Commenters supported the proposal to begin publicly reporting the refined measures in the fall of 2022. Commenters encouraged CMS to evaluate the inpatient volumes of each cancer hospital when determining specific time periods for public reporting, realizing that some cancer hospitals may have insufficient inpatient volumes to generate quarterly SIRs. Commenters also suggested that Hospital Compare provide comparisons of CAUTI and CLABSI rates among the PPS-exempt cancer hospitals themselves.

Response: We thank the commenters for their support. We recognize the importance of being able to provide sufficient data and will monitor performance trends prior to publicly reporting data on the refined CAUTI and CLABSI measures. We also reiterate that we intend to publicly report the CAUTI and CLABSI performance data for the PCHs participating in the PCHQR Program to enable data comparisons among PCHs.

After consideration of the public comments received, we are finalizing our proposal to begin publicly reporting the refined CAUTI and CLABSI measures in the fall of 2022. We are also finalizing our proposal to not publicly report the current versions of the measures.

6. Form, Manner, and Timing of Data Submission

Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website. We did not propose any updates to our previously finalized data submission requirements and deadlines.

7. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We did not propose any changes to this policy.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual payment update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the background for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42524).

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728). For further information on how measures are considered for removal, we refer readers to the regulations at 42 CFR 412.560(b)(3).

3. Quality Measures Currently Adopted for the FY 2022 LTCH QRP

The LTCH QRP currently has 17 measures for the FY 2022 LTCH QRP, which are set out in the following table:

Quality Measures Currently Adopted for the FY 2022 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Application of Functional Assessment	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH – Provider	Transfer of Health Information to the Provider Post-Acute Care
TOH – Patient	Transfer of Health Information to the Patient Post-Acute Care
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
DTC	Discharge to Community–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

Furthermore, LTCHs are required to report additional standardized patient assessment data beginning with the FY 2022 LTCH QRP. For more information on the reporting of this additional standardized patient assessment data, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42536 through 42590).

There were no proposals or updates to finalize for the LTCH QRP.

4. Form, Manner, and Timing of Data Submission Under the LTCH QRP

We refer readers to the regulations at 42 CFR 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

For more details about the required reporting periods of measures or standardized patient assessment data during the first and subsequent years upon adoption, please refer to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42588 through 42590).

5. Policies Regarding Public Display of Measure Data for the LTCH QRP

CMS is not finalizing any policies regarding the public display of measure data at this time.

6. Miscellaneous Comments

The proposed rule contained no LTCH QRP proposals. However, we received several comments on the LTCH QRP.

Comment: A few commenters expressed support for CMS's actions to

alleviate burden on providers arising from the COVID–19 Public Health Emergency (PHE.) A commenter was concerned about the reliability and accuracy of the measures due to the exempted data and urged CMS to conduct thorough analyses to ensure measure performance. Another commenter supported the idea to expand ICD–10–CM codes to capture additional Social Risk Factors (SRF) data.

Response: We appreciate the commenters' support and feedback. However, we consider these comments to be outside the scope of the current rulemaking. We refer providers to our June 23, 2020 announcement at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Spotlight-Announcements that, effective July 1, 2020 LTCHs must resume reporting their quality data.*

D. Changes to the Medicare and Medicaid Promoting Interoperability Programs

1. Background

a. Statutory Authority for the Medicare and Medicaid Promoting Interoperability Programs

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which included reporting on clinical quality measures using CEHRT. Incentive payments were available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that successfully demonstrate meaningful use of CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare generally are no longer available, except for Puerto Rico eligible hospitals. For more information on the Medicare incentive payments available to Puerto Rico eligible hospitals, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41672 through 41675).

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated EHR reporting periods. Section 1853(m)(4) of the Act establishes a negative payment adjustment to the monthly prospective payments of a qualifying MA organization if its affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015.

Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT. However, we previously established that in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after CY 2021 (§ 495.310(f), 75 FR 44319). Therefore, December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to CY 2021 or a prior year) (84 FR 42591 through 42592). For additional discussion or context around the discontinuation of the Medicaid Promoting Interoperability Program, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (*83 FR 41676* through 41677) and the CY 2019 PFS/QPP final rule (*83 FR 59704* through 59706).

2. EHR Reporting Period

a. EHR Reporting Period in CY 2022 for Eligible Hospitals and CAHs

Under the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, the EHR reporting period in CY 2021 is a minimum of a continuous 90-day period in CY 2021 for new and returning participants in the Promoting Interoperability Programs. Eligible hospitals and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 (from January 1, 2021 through December 31, 2021).

For CY 2022, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32853), we proposed an EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program. We stated that we believe that adopting a 90-day EHR reporting period in CY 2022 as in CY 2021 would be appropriate because it would provide programmatic consistency for hospital reporting for an additional year. We proposed corresponding changes to the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4. We did not propose to define an EHR reporting period in CY 2022 for the Medicaid Promoting Interoperability Program because the program will end with CY 2021 in accordance with section 1903(t)(5)(D) of the Act (see also 42 CFR 495.310(f)) as described previously. For additional discussion or context around the discontinuation of the Medicaid Promoting Interoperability Program, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41676 through 41677) and the CY 2019 PFS/QPP final rule (83 FR 59704 through 59706).

Comment: Many commenters supported the EHR reporting period proposal to continue the current policy of a minimum of any continuous 90-day period for CY 2022. Commenters emphasized how it would ease overall provider burden and offer healthcare systems stability as they work to implement other recent ONC 21st Century Cures Act final rule and CMS Interoperability and Patient Access final rule requirements related to interoperability, information blocking, and patient access).

Response: We thank commenters for supporting the CY 2022 EHR reporting period proposal. We agree that for CY 2022 keeping the EHR reporting period to a minimum of 90 days will afford eligible hospitals and CAHs the individual, site-specific flexibility they might need in order to update their EHR systems and implement new regulatory requirements such as in the ONC Cures Act final rule (85 FR 25642 through 25961). We note that the 90-day EHR reporting period is a minimum and eligible hospitals and CAHs are encouraged to use longer periods, up to and including the full CY 2022.

Comment: One commenter strongly supported the proposal as representative of CMS's goals for rural and small hospitals to help reduce provider burden, improve the use of electronic data exchange, and provide adequate support or flexibility in those communities lacking a sufficient IT workforce.

Response: We thank the commenter for sharing their input, as we continue to strive toward promoting greater interoperable strategies among these electronic systems. We believe such goals help to enhance the strengthened support utilized by all inpatient-stay systems, including those serving rural and small hospitals.

Comment: Several commenters encouraged CMS to consider making

this existing policy the standard amount of time for the EHR reporting period for future years or for the rest of the program. One commenter cited the existing systems-related workload around necessary assessments or functionality improvements and another concurred that 90 days is a sufficient amount of time to capture required information which reflects the highest utilization numbers. While the same commenters expressed support for this proposal for CY 2022, they also stated it would be beneficial to all if it was also continued past CY 2022.

Response: We thank the commenters for their support and suggestion to continue this policy beyond CY 2022. Although our proposal was limited to CY 2022, we will consider the commenters' suggestion for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal that for CY 2022, the EHR reporting period is a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program. We are finalizing, as proposed, the corresponding changes to the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

3. Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41656), we adopted two new opioid measures for the Electronic Prescribing objective; however, we changed certain policies related to those measures in the subsequent FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596): (1) Query of Prescription Drug Monitoring Program (PDMP), which was optional in CY 2019 and CY 2020 and worth 5 bonus points each year; and (2) Verify Opioid Treatment Agreement, which was optional in CY 2019 but removed entirely from the program starting in CY 2020.

b. Query of PDMP Measure

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42595), we finalized that the Query of PDMP measure is optional and eligible for 5 bonus points in CY 2020. We received substantial feedback from health IT vendors and hospitals that the flexibility currently included in the measure presents unintended challenges such as significant burden associated with IT system design and additional development needed to accommodate the measure and any future changes to it. Since publication of the FY 2020 IPPS/LTCH PPS final rule, stakeholders have continued to express concern that it is still too premature to require the Query of PDMP measure and score it based on performance in CY 2021.

We agree with stakeholders that PDMPs are still maturing in their development and use. PDMPs vary among the states and are not linked at this time to one another or to a larger national system.[498]

Stakeholders also mentioned the challenge posed by the frequent lack of integration of PDMPs into the clinical workflow. Historically, health care providers have had to go outside of the EHR in order to separately log in to and access a State PDMP. In addition, stakeholders noted the wide variation in whether PDMP data can be stored in the EHR. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions.

ONC recently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across States. This assessment explored factors like PDMP data integration, standards and hubs used to facilitate interstate PMDP data exchange, access permissions, and laws and regulations governing PDMP data storage. The assessment revealed ambiguous or non-existent policies regarding PDMP placement in health IT systems, interpretation of PDMP data, and PDMP access roles. One-third of hospitals have reported integration of PDMP queries within their EHR workflows.[499] In addition, variability in standards and hubs used to facilitate interstate PMDP data exchange, as well as to store and report PDMP data, contribute to the complexity of PDMPs.

The SUPPORT for Patients and Communities Act (Pub. L. 115–271),[500] enacted in 2018, is an important investment in combating the opioid epidemic. Several of the provisions of the SUPPORT for Patients and Communities Act address opioid use disorder prevention, recovery, and treatment, including increased access to evidence-based treatment and follow-up care, through legislative changes specific to the Medicare and Medicaid programs. Specifically, with respect to PDMPs, the SUPPORT for Patients and Communities Act included new requirements and federal funding for PDMP enhancement, integration, interoperability, and established mandatory use of PDMPs by certain Medicaid providers to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorder.

Section 5042(a) of the SUPPORT for Patients and Communities Act added section 1944 to the Act, titled ''Requirements relating to qualified prescription drug monitoring programs and prescribing certain controlled substances.'' Subsection (f) of section 1944 of the Act increased Medicaid FFP during FY 2019 and FY 2020 for certain state expenditures to design, develop, or implement a qualified PDMP (and to make subsequent connections to such program). As a condition of this enhanced FFP, states must meet the conditions described in section 1944(f)(2) regarding agreements with contiguous states. There are currently a number of states that have used, or are seeking to use, this enhanced FFP.

Under section 1944(b)(1) of the Act, to be a qualified PDMP, a PDMP must facilitate access by a covered provider to the following information (at a minimum) about a covered individual, in as close to real-time as possible: Information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period; and the name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at the least the most recent 12-month period. Under section 1944(b)(2) of the Act, a qualified PDMP must also facilitate the integration of the information described in section 1944(b)(1) of the Act into the workflow of a covered provider, which may include the electronic system used by the covered provider for prescribing controlled substances. CMS issued additional guidance to states about the enhanced FFP authorized by the SUPPORT for Patients and Communities Act, which can be found at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq051519.pdf.*

[498] See *https://namsdl.org/topics/pdmp/* and *https://www.pdmpassist.org/content/pdmp-maps-and-tables.*

[499] See ONC analysis of 2017 AHA survey data at: *https://www.healthit.gov/buzz-blog/health-it/new-data-show-nearly-one-third-of-hospitals-can-access-pdmp-data-within-their-ehr.*

[500] See *https://crsreports.congress.gov/product/pdf/R/R45449.*

Additionally, we note that section 7162 of the SUPPORT for Patients and Communities Act supports PDMP integration as part of the CDC's grant programs aimed at efficiency and enhancement by states, including improvement in the intrastate and interstate interoperability of PDMPs.

In support of efforts to expand the use of PDMPs, there are currently a number of federally supported activities underway aimed at developing a more robust and standardized approach to EHR–PDMP integration. Partners including CMS, CDC, ONC, and private sector stakeholders are focused on developing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. For instance, stakeholders are working to map the NCPDP SCRIPT standard version 2017071 and the 2015 ASAP Prescription Monitoring Program Web Service standard version 2.1A to the HL7® FHIR® standard version R4.[501] These mapping efforts are currently targeting completion by summer of 2020 after which the standard would be balloted. Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck which is a federally supported interstate exchange hub for PDMP data.[502] In addition, the ONC Interoperability Standards Advisory includes monitoring of current and emerging standards related to PDMP and OUD data capture and exchange that would allow a provider to request a patient's medication history from a State PMDP.[503] We believe these standards and technical approaches are likely to rapidly reach maturity and to support adoption across health care system stakeholders.

In addition to monitoring activities which can provide a stronger technical foundation for a measure focused on PDMP use, we also requested comments in the FY 2020 IPPS/LTCH PPS proposed rule on alternative measures designed to advance clinical goals related to the opioid crisis (84 FR 19568 and additional comment responses in the FY 2020 IPPS/LTCH PPS final rule in 84 FR 42593 through 42595). Specifically, we sought public comment on the development of potential measures for consideration for the Promoting Interoperability Program that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including opioid quality measures endorsed by the National Quality Forum (NQF) and CDC Quality Improvement (QI) opioid measures based on CDC guidelines around prescribing practices. The latter of these includes the use of electronically-specified CDS to support OUD prevention and treatment best practices and the integration of a PDMP query as a part of specific clinical workflows. We stated that these measures relate to a range of activities that hold promise in combatting the opioid epidemic as part of OUD prevention and treatment best practices, that they can be supported using CEHRT, and that they may include the use of PDMP queries as a tool within the broader clinical workflows. We continue to evaluate the comments received in response to this request for information, and will explore how measures such as those discussed may help participants to better understand the relationship between the measure description and the use of health IT to support the actions of the measures related to opioid use.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to specify a single approach to EHR–PDMP integration at this time. At the same time, we have heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust certification specifications and standards. These stakeholders stated that health IT developers may face significant cost burdens under the current flexibility allowed for health care providers if they either fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Stakeholders have noted that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure (for a summary of public comments discussed in last year's final rule, we refer readers to 84 FR 42593 through 42595, continued from last year's proposed rule in 84 FR 19556 through 19558).

Given current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns as previously discussed about the current readiness across states for implementation of the existing measure, we believe that additional time is needed prior to requiring a Query of PDMP measure for performance-based scoring. While we appreciate the concerns that stakeholders have shared, we believe that this measure can play an important role in helping to address the opioid crisis. Maintaining it as an optional measure with bonus points signals to the hospital and vendor community that this is an important measure which addresses a current gap that can help to spur development and innovation to reduce the barriers and challenges expressed to CMS.

Therefore, we proposed for CY 2021 to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points, as well as corresponding changes to the regulation at § 495.24(e)(5)(iii)(B) (85 FR 32853 through 32855). Continuing to include the measure as optional in CY 2021 would allow time for further progress around EHR–PDMP efforts minimizing the burden on eligible hospitals and CAHs reporting while still providing an opportunity for capable implementers to report on and earn 5 bonus points for the optional measure. We sought comments on our proposal to maintain the Query of PDMP measure in CY 2021 as optional and worth 5 bonus points.

Comment: The majority of commenters agreed with the proposal to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021. Several of the comments expressed support given their concerns over how current workflows may require providers to repeatedly log into multiple, separate databases in order to manually enter patient data into CEHRT and document completion of the measure's query. One of the commenters raised a concern where non-integrated state PDMPs lead to data-entry by hand which can increase the probability of human errors related to erroneous patient-matching or documentation.

[501] See *http://hl7.org/fhir/us/meds/pdmp.html.*

[502] See *https://www.pdmpassist.org/RxCheck.*

[503] See *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

Response: We thank commenters for their continued support regarding the Query of PDMP measure. We recognize that various state programs are still maturing toward the development of fully fledged EHR–PDMP integration. We continue to collaborate with our partners in ONC, on how to advance standards surrounding PDMP functionality and integration. Keeping the Query of PDMP measure as optional for CY 2021 would allow states and other stakeholders an additional year to make further progress on developing functionality to support better integration of PDMP use within clinical workflows.

Comment: Two commenters who agreed with the proposal requested clarification that the measure would continue to require a yes/no response as finalized in previous rules.

Response: We appreciate these commenters support. The measure will continue to require a yes/no attestation response for CY 2021.

After consideration of the public comments we received, we are finalizing our proposal for CY 2021 to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points, as well as finalizing corresponding changes to the regulation at § 495.24(e)(5)(iii)(B) as proposed.

4. Health Information Exchange Objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41659 through 41661), we established a new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure by combining the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure. In establishing the new measure, we did not change the specifications or actions associated with the two combined measures, which address receiving an electronic summary of care record and conducting reconciliation of the summary of care record. However, the name of the measure includes the word ''incorporating,'' which is not always an action that is required for purposes of meeting the numerator of the measure. Instead, clinical information reconciliation must be completed using CEHRT for the following three clinical information sets: (1) Medication; (2) Medication Allergy; and (3) Current Problem List. In addition, we established that for cases in which the eligible hospital or CAH determines no update or modification is necessary within the patient record based on the electronic clinical information received, the eligible hospital or CAH may count the reconciliation in the numerator without completing a redundant or duplicate update to the record (83 FR 41661). Thus, we proposed to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to better reflect the actions required by the numerator and denominator (85 FR 32855). We proposed to replace the word ''incorporating'' with the word ''reconciling'' such that the new name would read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, and to codify this change at § 495.24(e)(6)(ii)(B). We sought comments on our proposals.

Comment: Many commenters supported the proposal to modify the measure's name by replacing the word ''incorporating'' with the word ''reconciling'' to better reflect the measure's intent and reduce confusion on the actions required for the numerator and denominator calculation.

Response: We thank the commentators for their input and agree that the new name, Support Electronic Referral Loops by Receiving and Reconciling Health Information, best reflects the measure's intent relating to the specific actions required in calculating the numerator and denominator.

Comment: Two commenters did not believe that the name should be updated and stated that the measure modification could lead to unnecessary administrative burden and tedious documentation edits.

Response: While the updating of the name may require edits to existing documentation in EHR systems or reports, we disagree that this update would alone outweigh the benefit of implementing programmatic improvements to reduce potential confusion caused by the measure's existing name. The measure specifications establish that no duplicative update is necessary within the patient record based upon the clinical information received, only that it must be compared against what is currently available (a reconciliatory act, as indicated in the measure's current specification sheet).[504] In agreement with the majority of commenters, we see the name change as more clearly reflecting the existing policy that the measure is not requiring providers to input redundant information, but rather to review and reconcile what is received with what is already in the patient record.

After consideration of the public comments we received, we are finalizing our proposal to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure such that the new name will read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. In addition, we are also finalizing the corresponding changes at § 495.24(e)(6)(ii)(B) as proposed.

5. Scoring Methodology for Eligible Hospitals and CAHs Attesting to CMS Under the Medicare Promoting Interoperability Program for an EHR Reporting Period in CY 2021

The following table reflects the objectives and measures as finalized for CY 2021. As discussed in sections VII.D.3 and VII.D.4 in the preamble of this final rule, we are finalizing our proposals for CY 2021 to include: (1) Changing the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, and (2) the continuation of the optional Query of PDMP measure worth 5 bonus points for CY 2021.

[504] See *https://www.cms.gov/files/document/medicare-eh-2020-support-electronic-referral-loops-receiving-and-incorporating-information.pdf.*

Performance-Based Scoring Methodology
EHR Reporting Period in CY 2021

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	5 points (*bonus*)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information *	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose any two: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting • Electronic Reportable Laboratory Result Reporting	10 Points

Notes: The Security Risk Analysis measure is required, but will not be scored;
The information blocking attestation statements are required, but will not be scored;
eCQM measures are required, but will not be scored.
Measure with a name change in this final rule is denoted with an asterisk (*)

6. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare and Medicaid Promoting Interoperability Programs

a. Background and Current Clinical Quality Measures

Under sections 1814(l)(3)(A), 1886(n)(3)(A), and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (CQMs; also referred to as electronic CQMs, or eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid Promoting Interoperability Programs. However, as previously established in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after CY 2021 (§ 495.310(f), 75 FR 44319). Therefore, December 31, 2021 is the last date that states could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year) (84 FR 42591 through 42592).

The following table lists the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid Promoting Interoperability Programs (84 FR 42597 through 42599) for the reporting period in CY 2021 and subsequent years, including the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e), finalized as mandatory for reporting beginning with CY 2022 (84 FR 42598 through 42600).

CQMs for Eligible Hospitals and CAHs for CY 2021 and Subsequent Years

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients (ED-2)	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

b. eCQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CYs 2021, 2022, and 2023

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32856 through 32857), consistent with a similar proposal under the Hospital IQR Program in the same proposed rule (85 FR 32836 through 32837), we proposed to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a 3-year period. Specifically, we proposed to require two self-selected calendar quarters of data from CY 2021, three self-selected calendar quarters of data from CY 2022, and four calendar quarters of data beginning with CY 2023. We stated that we believe increasing the number of quarters for which hospitals are required to report eCQM data would produce more comprehensive and reliable quality measure data for patients and providers. Taking an incremental approach over a 3-year period would also give hospitals and their vendors time to plan in advance, build upon, and utilize investments already made in their existing EHR infrastructure. Additionally, reporting multiple quarters of data would provide hospitals with a more continuous stream of information to monitor their levels of performance, as ongoing, timely data analysis can better identify a change in performance that may necessitate investigation, and potentially corrective action. We also refer readers to section VIII.A.9 of the preamble of this final rule for a discussion of similar proposals made for the Hospital IQR Program.

(1) Changes to the eCQM Reporting Period in CY 2021

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42599 through 42600), we established the eCQM reporting periods, reporting criteria, and submission periods for CY 2021. We refer readers to that final rule for a more detailed discussion of our previously established final policies. Consistent with our proposal for the Hospital IQR Program in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32856), we proposed to modify the eCQM reporting period in CY 2021 under the Medicare and Medicaid Promoting Interoperability Programs for eligible hospitals and CAHs that report CQMs electronically. Specifically, we proposed to require eligible hospitals and CAHs to report two self-selected calendar quarters of eCQM data from CY 2021, on four self-selected eCQMs from the set of available eCQMs, for CY 2021 as previously established (84 FR 42599 through 42600).

(2) Changes to the eCQM Reporting Period in CY 2022

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42600), we established the eCQM reporting periods, reporting criteria, and submission periods for CY 2022. We refer readers to that final rule for a more detailed discussion of our previously established final policies. Consistent with our proposal for the Hospital IQR Program in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32856), we proposed to modify the eCQM reporting period in CY 2022 under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs that report eCQMs electronically. Specifically, we proposed to require eligible hospitals and CAHs to report three self-selected calendar quarters of eCQM data from CY 2022, for each required eCQM as previously established (84 FR 42600): (a) Three self-selected eCQMs from the set of available eCQMs for CY 2022, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM.

(3) Reporting and Submission Requirements for eCQMs for CY 2023 and Subsequent Years

For CY 2023 and each subsequent year, we proposed to require eligible hospitals and CAHs reporting CQMs for the Medicare Promoting Interoperability Program to report 4 calendar quarters of data from CY 2023 and each subsequent year (85 FR 32856 through 32857) for: (a) 3 self-selected eCQMs from the set of available eCQMs for CY 2023 and each subsequent year; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of 4 eCQMs. As finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42601 through 42602), attestation is no longer a method for reporting eCQMs for the Medicare Promoting Interoperability Program, beginning with the reporting period in CY 2023, and instead, all eligible hospitals and CAHs are required to submit their eCQM data electronically through reporting methods made available through the Hospital IQR Program. Additionally, we proposed that the submission period for the Medicare Promoting Interoperability Program would be during the 2 months following the close of the respective calendar year. For example, the submission period for CY 2023 would be the 2 months following the close of CY 2023, ending February 28, 2024, and the same 2-month pattern would follow for each subsequent year.

Comment: Many commenters supported our proposal to increase the number of quarters for which hospitals are required to report eCQM data. Some commenters specifically appreciated CMS's plan to phase in the requirement over three years because they believe a progressive approach will allow hospitals and vendors sufficient time to implement the proposal without being overly burdensome. Other commenters stated the proposal will improve accuracy and reliability of data, provide a more accurate picture of overall hospital performance, increase hospital accountability, and reduce the likelihood that hospitals will report only on their top-performing quarter. Commenters also stated the proposal would enable hospitals and other stakeholders to successfully monitor performance trends, particularly through the CMS *Hospital Compare* site, or successor websites, and enhance patient outcomes.

Response: We thank the commenters for their support. We believe increasing eCQM reporting over a 3-year period will help to ease the burdens associated with reporting larger amounts of data, and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting. We believe the long-term benefits associated with reporting a full year of electronic data will outweigh the burdens, and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers.

Comment: A few commenters recommended that we phase in the increased requirements at a faster rate, such as over a 2-year period instead of a 3-year period.

Response: We thank the commenters for their recommendations. We considered a faster implementation timeline in developing our proposals, but ultimately determined to propose to align with the Hospital IQR Program's proposal to progressively increase the number of required quarters of eCQM data over a 3-year period in order to continue to give hospitals and their vendors time to plan in advance and build upon and utilize investments already made in their EHR infrastructure (85 FR 32837). We believe this approach effectively balances the burdens associated with increased reporting of eCQM data and the benefits of providing that quality data to patients and consumers.

Comment: Many commenters did not support the proposal to require additional quarters of eCQM data given the impact of the COVID–19 public health emergency (PHE) on hospitals, and requested that eCQM reporting and submission requirements for the CY 2021 reporting period remain at one self-selected calendar quarter of data for each of the four self-selected eCQMs. Commenters stated that the COVID–19 PHE has shifted focus from normal operations toward increased burden and strained hospital resources, particularly impacting staffing and technology. A few commenters indicated that the COVID–19 PHE has limited hospitals' ability to make the IT investments needed to report additional quarters of data. Commenters stated that internal resources have been reallocated or reassigned, that current IT investments are focused on caring for COVID–19 patients via telehealth, and that hospitals are already experiencing burdens or costs associated with implementing additional regulations on information blocking and interoperability. Commenters also stated that hospitals are complying with numerous federal and state data reporting requirements related to COVID–19 lab testing, patient volumes, and bed capacity, which are constantly evolving. The commenters stated that, while the duration of the COVID–19 PHE remains uncertain, hospitals expect to be operating in this challenging environment well into CY 2021.

Given these challenges, commenters requested that reporting and submission requirements for the CY 2021 reporting period remain at one self-selected calendar quarter of data so that hospitals may choose the fourth quarter, providing additional time for EHR upgrades. A few commenters expressed concern that the proposal could cause hospitals to lose their entire annual payment update for failing to meet an eCQM mandate that their EHR vendors cannot deliver, due to the pandemic and other competing federal EHR-related mandates. One commenter stated that the COVID–19 PHE's impact on hospital volumes may render data less reliable. Another commenter suggested that CMS continue to monitor the COVID–19 PHE, and the extent to which hospitals have recovered, to inform the exact timeframe to begin increasing eCQM reporting requirements.

Response: We thank commenters for their comments and recognize the burden that the COVID–19 PHE has had on the healthcare system. In response to the significant impact of the COVID–19 PHE on hospitals, CMS issued an array of temporary regulatory waivers and exceptions affecting a wide cross-section of Medicare participation, eligibility, and payment requirements in an effort to reduce burden, provide flexibility to hospitals, and help hospitals maximize their capacity to focus on patient care.[505] These waivers and exceptions reduce hospital paperwork burden and reporting requirements, increase flexibility for surge capacity and patient quarantine, allow providers to expand access to telehealth, and enable hospitals to enhance their workforces, among other benefits. Specific to the Promoting Interoperability Program, we issued a hardship exception extension, allowing eligible hospitals additional time to submit these requests.[506]

Our current policy for eCQM reporting requires hospitals to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2020 reporting period. We believe that a single quarter of data is not enough to capture trends in performance over time, therefore our goal in proposing to progressively increase the number of quarters of data to be collected over 3 years was to strike an appropriate balance between increasing eCQM reporting and providing hospitals with the necessary time to implement such changes.

Comment: A commenter did not support the proposal to increase the number of self-selected quarters of eCQM data that hospitals must support for the CY 2021 reporting period. The commenter stated that given the unknown future of the impact of the COVID–19 PHE, any increase in eCQM submissions for CY 2021 could have a significant detrimental impact on small, rural hospitals, particularly because many of these hospitals do not find the current eCQMs (including the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e), finalized as mandatory for reporting beginning with CY 2022) to be meaningful to their quality improvement. The commenter stated that because mandatory reporting on the Safe Use of Opioids-Concurrent Prescribing measure (NQF #3316e) begins in CY 2022, it would be beneficial to evaluate the usefulness and challenges of extracting this data after one quarter, rather than requiring two quarters.

Response: As previously established in rulemaking, for the CY 2021 reporting period, hospitals will continue to report on four self-selected eCQMs, and reporting on the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM) will not be required until the CY 2022 reporting period. The Safe Use eCQM will be included in the eCQM subset beginning with the CY 2021 reporting period, and a hospital may voluntarily select to report on the Safe Use eCQM on two quarters of data at that time.

With respect to the usefulness and challenges of extracting eCQM data after one quarter rather than requiring two quarters, we believe that our proposal further advances our goal of increasing the use of EHR data for quality measurement and improvement. We believe that reporting on the Safe Use eCQM will provide valuable information in the area of high-risk prescribing to providers, and further our efforts to combat the negative impacts of the opioid crisis. Last, we appreciate that there may be challenges with extracting data for the Safe Use eCQM. Although this measure was developed being mindful that logistically, the implementation of the data extraction process needed to be feasible, we will be considerate of this feedback in future rulemaking.

Regarding the meaningfulness of eCQMs in small, rural hospitals—rural health continues to be one of our top priorities. In 2016, we established an agency-wide Rural Health Council, and in 2017 we launched the Meaningful Measures Initiative and included Improving Access for Rural Communities as an initiative. Additionally in 2017, we tasked the National Quality Forum (NQF) to establish a Measure Applications Partnership (MAP) Rural Health Workgroup to identify a core set of the best available rural-relevant measures to address the needs of the rural population and provide recommendations from a rural perspective regarding measuring and improving access to care.[507] When selecting eCQMs for inclusion in the measure set, we have, and will continue to consider the recommendations from the rural providers to ensure eCQMs are meaningful to quality improvement for small, rural hospitals.

In response to concerns regarding the future of the impact of the COVID–19 PHE, we will continue to monitor the impact that the COVID–19 PHE has on

[505] See *https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.*

[506] See *https://www.cms.gov/files/document/medicare-pi-hardship-fact-sheet-2020.pdf.*

[507] See Measures Application Partnership, ''A Core Set of Rural-Relevant Measures and Measuring and Improving Access to Care: 2018 Recommendations from the MAP Rural Health Workgroup'' (Aug. 31, 2018), available at *https://www.qualityforum.org/Publications/2018/08/MAP_Rural_Health_Final_Report_-_2018.aspx.*

hospitals, including small, rural hospitals, and will issue additional guidance as appropriate. Please also see our previous responses, specifically addressing the COVID–19 PHE.

Comment: Many commenters requested that CMS adopt a more incremental approach for increasing the eCQM reporting requirements. A few of the numerous alternative approaches recommended by commenters included postponing the proposed increase in data reporting for one calendar year, postponing the increase until the COVID–19 PHE has abated and hospital volumes return to pre-pandemic levels, and increasing the number of calendar quarters of data to be reported by one quarter every other year.

Response: As noted previously, after delaying the increased eCQM reporting requirements for a number of years, we believe our proposal to progressively increase the number of quarters of eCQM data to be collected over a three-year period strikes an appropriate balance between increasing eCQM reporting and providing hospitals with the necessary time to implement such changes. We understand the desire to postpone the increased reporting requirements until the pandemic has abated, and hospital volumes return to pre-pandemic levels, and note that we proposed requiring hospitals to report only two quarters of data for the CY 2021 reporting period. We note that hospitals may choose to report data from the third and fourth quarters of CY 2021, which may have higher volumes, and data would not need to be reported until the end of the data submission period (that is, by the end of February 2022). Specific to the Promoting Interoperability Program's response to COVID–19 PHE, we issued a hardship exception extension, allowing eligible hospitals additional time to submit these requests. Please also see our previous responses, specifically addressing the COVID–19 PHE.

Comment: Several commenters raised concerns about the accuracy, reliability, and validity of eCQM data. One commenter stated the data produced by chart-abstracted measures and eCQMs vary significantly. A few commenters recommended that CMS adopt a more incremental approach to increasing eCQM reporting requirements, or delay its proposal altogether until at least CY 2023, to balance benefits with burdens and better ensure reliability and validity for measurement. A commenter stated that it would be premature for CMS to require electronic reporting before all measures are fully electronically specified and field tested. The commenter emphasized the need for providers to have detailed electronic specifications in advance in order to adequately prepare their reporting systems. Another commenter encouraged CMS to evaluate how each additional quarter of data improves accuracy and reliability prior to further increasing the number of required quarters.

Response: We understand the commenters' concern about data reliability and validity and wish to emphasize that all types of quality measures, including eCQMs, undergo testing during the measure development process for feasibility, validity, and reliability. We also recognize that EHR-based extraction methodology for eCQMs is different from the data collection methodology for chart-abstracted measures, and that measure rates may vary depending on methodology (80 FR 49643 through 49644).

For example, eCQMs utilize data from structured fields within the EHR system, while chart-abstracted measures allow data to be collected from unstructured sources such as a clinician's progress notes. For these reasons, we use a validation process to address concerns about reliability and validity of eCQM data. Together, alongside the Hospital IQR Program (as described in section VIII.A.10. of the preamble of this final rule), we are continuously working to improve the eCQM validation process and balance reporting burden. We expect to gain a better understanding of how to continue to increase the accuracy of eCQM data by continuing to analyze and improve upon that process. We do believe that the reporting of additional quarters of data by hospitals will help to increase the reliability of the data, and we also note that measure specifications are typically available about eight months prior to the beginning of the calendar year reporting period.

Comment: A few commenters expressed concern about the amount of time that may be required for a hospital or their vendor to internally validate the data, and/or create and review CCN files prior to data submission to CMS. One commenter stated the proposal amends more modest, previously finalized policies that hospitals relied on for planning and resource allocation purposes.

Response: We recognize that increasing the number of quarters of eCQM data to be reported can impact a hospital's resource use, and refer readers to section XI. B.9 of the preamble of this final rule for a detailed discussion on our burden estimates associated with eCQM reporting and submission. We believe the long-term benefits associated with reporting a full year of electronic data will outweigh these burdens and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers. We believe that taking an incremental approach to increasing eCQM reporting over a three-year period will help to ease the burdens associated with reporting larger amounts of data and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting.

Comment: One commenter did not support the proposal because they believed it contradicted the trend to make the program simpler. Another commenter stated there is increased burden on hospitals due to duplications of effort in reporting the same measures in both chart-abstracted and eCQM formats.

Response: We disagree with the commenter that the proposal contradicts our efforts to make the program simpler. Since October of 2017, we have undertaken an ambitious effort to reduce regulatory burden on the healthcare industry, lower health care costs, and enhance patient care by streamlining the quality reporting programs through the Meaningful Measures initiative. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a broader discussion of the Meaningful Measures framework (83 FR 41147). In recent years, we have also improved and continued to maintain alignment between the Promoting Interoperability Program and the Hospital IQR Program, such that we now have the same eCQMs and data submission requirements. We will continue to look across all quality programs to identify areas to further streamline, and opportunities to reduce any remaining duplicative efforts.

Comment: One commenter did not support the proposed expansion of eCQM reporting or public reporting until problems with validation of eCQM data are addressed. The commenter stated that hospitals participating in eCQM data validation continue to report unresolved concerns, such as the inability to authenticate validation results provided for 2017 and 2018 because mismatches on the validation reports were not specifically identified. The commenter stated that hospitals and vendors need a better understanding of the cause of mismatches and how to correct them in advance of any public reporting, and recommended CMS make improvements

to the validation procedures and reports. A few commenters requested that CMS provide additional transparency into the eCQM validation process before increasing the number of quarters required to be reported, such as information on eCQM agreement rates, national eCQM scores, the effect of invalidated data on national and hospital-specific scores, comparisons of the current eCQM data against previously collected chart-abstracted data, and an analysis on how eCQM scores are affected by using the chart-abstracted measure specifications and algorithms for validation. Last, commenters requested that CMS provide an analysis of how self-selection of individual eCQMs by each hospital affects national averages, and the number of hospitals reporting on each measure.

Response: We appreciate the feedback from hospitals on their experiences with the eCQM validation process. The specifications for eCQMs contain logic statements and value sets tailored to electronic data sources, and as such, measure specifications and algorithms for chart-abstracted measures are not used for eCQM validation. As the Hospital IQR Program further describes in sectionVIII.A.10 of the preamble of this rule, together, we are continuously working to improve eCQM validation and are finalizing several changes to that process. Our decision to extend the educational review process established for chart-abstracted measure validation to eCQM validation may be of particular interest to stakeholders. We would also like to refer commenters to the eCQM validation resources available on QualityNet.[508]

Comment: A few commenters stated that the required updates to EHRs to modify eCQMs often take significant implementation resources before hospitals are able to report eCQM data. The commenters expressed concern that the proposed increase in data reporting requirements would shorten the timeframe for hospitals to make and validate required measure logic changes, which would require hospitals to expend additional resources in order to finish changes on time. The commenters requested that CMS provide hospitals with 18 months to implement changes.

Response: We disagree that there is not enough time to implement eCQM data measure reporting requirements. We note that the eCQM specifications are typically available around eight months prior to the beginning of the calendar year of the reporting period. We also believe that once the eCQM updates are implemented in hospital EHRs, reporting an additional quarter of data should not require the same level of effort as reporting one initial quarter of data. Thus, we do not expect hospitals to experience a significant amount of added burden reporting three additional quarters of data over a three-year period. We would like to note that we did not propose to modify, remove, or add any additional eCQM measures to the Promoting Interoperability Program in the FY 2021 IPPS/LTCH PPS proposed rule. We do thank the commenters for their feedback and will take this information into account when modifying and aligning the eCQM measure set in future rulemaking.

Comment: A few commenters expressed concern about variation in readiness and eCQM reporting capabilities across hospitals. Commenters recommended that CMS work with stakeholders to identify underlying structural problems and barriers to successful reporting; consider a process by which hospitals could request and receive a one-year extension, if needed, to increase their eCQM reporting to four calendar quarters, or take a more incremental approach to increasing eCQM reporting requirements.

Response: As stated previously, we have reduced the number of eCQMs, and delayed eCQM reporting requirements over a number of years in order to allow hospitals and vendors additional time to upgrade IT systems, improve data mapping and other capabilities, and increase staff training for eCQM reporting. In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to progressively increase the number of quarters of data to be collected over three years to continue to give providers time to gain experience with eCQM reporting and submission. We believe that gradually increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality measure data for patients and providers. We will continue to work with stakeholders to identify any structural issues or barriers to successful reporting.

Comment: Several commenters requested clarification about the data submission process associated with increasing the number of quarters of data required to be reported. Specifically, commenters requested that CMS clarify the timing of submission deadlines and the ability of hospitals to report non-consecutive quarters of data. One commenter requested that CMS clarify that until all four quarters of data are required, the hospital will be able to self-select which quarters it reports on.

Response: In the FY 2021 IPPS/LTCH PPS proposed rule, our proposals would allow hospitals to self-select the calendar quarters of data to report for CYs 2021 and 2022, with data submission in the two months following the close of the calendar year (85 FR 32856 through 32857). Thus, the data submission deadline for eCQM data under the Promoting Interoperability Program, regardless of how many quarters of data are required to be reported for a given calendar year, will continue to be by the end of the 2 months following the close of the respective calendar year. The ability to self-select calendar quarters would enable hospitals to submit non-consecutive quarters of data of their choice. More specifically, we proposed to require that hospitals report two self-selected calendar quarters of data for each of the four self-selected eCQMs for the CY 2021 reporting period, three self-selected calendar quarters of data for the CY 2022 reporting period for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM (85 FR 32837). Hospitals would self-select the quarters it reported on until all four quarters were required, as proposed for the CY 2023 reporting period. The ability self-select quarters would permit hospitals to submit non-consecutive quarters of data.

Comment: A few commenters recommended that CMS monitor implementation of the proposal, such as soliciting feedback from hospitals to learn about reporting challenges and to ensure that the proposal does not impose substantial additional administrative burdens during the COVID–19 PHE. One commenter recommended that CMS work with stakeholders to ensure eCQM data provides actionable insights that support performance improvement, considering the burden required to report it.

Response: We thank the commenters for their suggestions. We plan to monitor the implementation of the increased reporting requirements for eCQM data alongside the Hospital IQR Program, and welcome continued feedback from stakeholders through webinars, listservs, and help desk questions. Finally, see our previous discussion on our approach with the COVID–19 PHE.

After consideration of the public comments we received, we are finalizing all of our proposals as proposed to progressively increase, over a 3-year period, the number of calendar

[508] See eCQM Data Validation Resources are available on QualityNet at: *https://www.qualitynet.org/search?q=validation.*

quarters that eligible hospitals and CAHs are required to report eCQM data for the Promoting Interoperability Program. For the CY 2021 reporting period, hospitals will be required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs, and the quarters chosen do not need to be consecutive. For the CY 2022 reporting period, hospitals will be required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM. For the CY 2023 reporting period and subsequent years, hospitals will be required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM, and the submission period for the Medicare Promoting Interoperability Program will be the 2 months following the close of the respective calendar year.

c. Public Reporting of eCQM Data

Electronic reporting serves to further the CMS and HHS policy goals to promote quality through performance measurement and, in the long-term, improve the accuracy of the data and reduce reporting burden for providers. It also promotes the continued effort to align the Promoting Interoperability Program with the Hospital IQR Program through simplifying and streamlining quality reporting. We expect that over time, hospitals will continue to leverage EHRs to capture, calculate, and electronically submit quality data, build and refine their EHR systems, and gain more familiarity with reporting eCQM data. As eCQM reporting continues to advance, and hospitals have gained several years of experience with successfully collecting and reporting eCQM data, it is important to further our policy goals of leveraging EHR-based quality measure reporting in order to incentivize data accuracy, promote interoperability, increase transparency, and reduce long-term provider burden by providing public access to the eCQM data being reported.

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. In the proposed rule, we stated that the current Hospital IQR Program policy is to report data as soon as it is feasible on CMS websites such as the Hospital Compare and/or its successor website after a 30-day preview period (78 FR 50776 through 50778). For additional information, we referred readers to section VIII.12.a. of the proposed rule, the Hospital IQR Program's Public Display Requirements.

Section 1886(n)(4)(B) of the Act requires the Secretary to post on the CMS website, in an easily understandable format, a list of the names of the eligible hospitals and CAHs that are meaningful EHR users, and other relevant data as determined appropriate by the Secretary. We believe other relevant data could include clinical quality measure performance rates, and data intended to improve transparency and reporting accuracy, because such data would enable patients, consumers, and health care providers to make informed decisions about their own, and their patients' healthcare.

Section 1886(n)(4)(B) of the Act also requires the Secretary to ensure that an eligible hospital or CAH has the opportunity to review the other relevant data that are to be made public with respect to the eligible hospital or CAH prior to such data being made public. By publicly reporting clinical quality measure data, this demonstrates our commitment to providing data to patients, consumers, and providers as quickly as possible to assist them in their decision-making.

Therefore, in alignment with our goal to encourage data accuracy and transparency, we proposed to align with the Hospital IQR Program in publicly reporting eCQM data submitted by eligible hospitals and CAHs for the Promoting Interoperability Program starting with the CY 2021 reporting period, and continuing through subsequent years (85 FR 32857). We stated that this data could be made available to the public as early as the fall of CY 2022. We also refer readers to section VIII.A. of the preamble of this final rule for a discussion of a similar proposal under the Hospital IQR Program.

Comment: A few commenters supported public reporting of eCQM data for the CY 2021 reporting period, with this data being made available to the public as early as Fall 2022. One commenter stated the proposal strikes a balance between reducing the administrative burden for providers of collecting and reporting eCQM data, without sacrificing the meaningfulness of quality information available to the public, and also ensuring that CMS has a more robust dataset to make payment decisions. One commenter found the proposed change reasonable and appropriate, and agrees that the current submission requirement does not effectively capture performance trends. A few commenters appreciated the greater public disclosure of eCQM data and agreed that the proposed change will provide a more accurate picture of overall performance for hospitals.

Response: We thank commenters for their support. We believe it is important to provide data to the public as soon as practicable while increasing the amount of eCQM data to be reported to CMS. We believe that beginning to publicly report eCQM data as early as the fall of 2022, while simultaneously progressively increasing the quarters of reported eCQM data strikes the appropriate balance between the importance of transparency by publicly reporting eCQM data and stakeholder concerns about using sufficient data for publicly reporting eCQM data.

Comment: A few commenters did not support public reporting of eCQM data from the CY 2021 reporting period beginning as early as Fall 2022 due to the impact of the COVID–19 PHE on hospitals, including needing to reassign and reduce hospital staff, redirect resources, and concerns about increasing provider burden. A few commenters did not support our proposal to publicly report eCQM data due to concern about measure performance during the COVID–19 PHE. Several commenters opposed publishing data on *Hospital Compare* for the CY 2021 reporting period, and recommended a delay until the CY 2022 reporting period or later due to the COVID–19 PHE that may impact the validity and reliability of data, especially when comparing performance across hospitals. A few commenters supported the proposal to publicly report eCQM data, but recommended that CMS confer with hospitals to ensure data reporting for the CY 2021 reporting period will not impose unreasonable administrative burden during the COVID–19 PHE.

Response: We continue to closely monitor and analyze the impact that the unpredictable nature that the COVID–19 PHE may have on the national comparability of Promoting Interoperability Program measures, as well as burden on hospitals, and will continue to communicate through routine channels as necessary. We appreciate commenters' concerns regarding the impact COVID–19 PHE has had on hospitals, however, we do

not believe that public reporting of eCQM data adds to that burden, as public reporting will not change how hospitals submit or report their eCQM data, nor the number of measures that will be required to be reported. For clarification, CY 2020 reporting period data will not be publicly reported, as we are finalizing to start public reporting of eCQM data with the CY 2021 reporting period in Fall of 2022.

Comment: Some commenters did not support public reporting of eCQM data due to the burden for some hospitals to successfully submit eCQM data.

Response: We understand commenters' concerns, however, we believe we have sufficiently mitigated any potential burden for hospitals by taking an incremental approach to allow hospitals to become familiar with eCQM reporting, prior to publicly reporting eCQM data.

Comment: Many commenters did not support public reporting of eCQM data as early as Fall 2022, and recommended a delay in public reporting to provide hospitals with additional time to prepare, to provide greater technical consistency, or until four quarters of data are required to be reported.

Response: We appreciate the commenters' feedback, but disagree that hospitals need more time to prepare for public reporting of eCQM data. CY 2021 will be the fifth year of mandated reporting of eCQM data for hospitals, and we have determined that eCQM data is accurate enough to begin reporting. While we appreciate commenters' concerns about public reporting eCQM data representing fewer than four quarters of data, we disagree that this should inhibit the advancement of public reporting of eCQM data. We believe it is important to provide data to the public as soon as practicable, while simultaneously increasing the amount of eCQM data being reported to CMS. We believe that beginning to publicly report eCQM data as early as the fall of 2022, while progressively increasing the quarters of reported eCQM data appropriately balances the importance of transparency by publicly reporting eCQM data and stakeholder concerns about using sufficient data for publicly reporting eCQM data. Last, we refer commenters to section VIII.A.9.b. of the preamble of this final rule, where the Hospital IQR Program references technical specifications for quality measures, and in addition, the FY 2019 IPPS/LTCH final rule where the Hospital IQR Program summarizes technical measure specifications for quality measures, and the sub-regulatory process for incorporation of non-substantive updates to the measure specifications.

Comment: Many commenters did not support public reporting of eCQM data beginning as early as Fall 2022, citing concern that inconsistency in the number of cases reported and the self-selection of eCQMs reported across individual hospitals might not accurately depict hospital performance. These commenters recommended aligning the start of public reporting with one consistent mandated eCQM across all hospitals.

Response: We acknowledge the commenters' concerns, however, we plan to initially publish CY 2021 eCQM data, consisting of two self-selected quarters of data, on *https://data.Medicare.gov* or its successor website, before publishing it on *Hospital Compare,* or its successor website. The Data.Medicare.gov website or its successor website, provides the public with access to downloadable datasets to ensure the information is publicly available, but does not offer side-by-side comparison capabilities like *Hospital Compare* or its successor website, without additional data management by the user. As more eCQM data are progressively reported, we will then display the additional information on the *Hospital Compare* website, or its successor website, where more direct comparisons of hospital performance will be available. We believe these finalized policies address the commenters' concerns while providing flexibility for hospitals and their vendors to build upon and utilize investments in their EHRs.

Comment: Several commenters did not support our proposal to publicly report eCQM data for the CY 2021 reporting period and to provide hospitals the opportunity to review the data. These commenters recommended a dry run with one quarter and two quarters of data to enable hospitals to preview their performance and national comparison data confidentially before the data are made public. Commenters recommended CMS conduct reliability analyses to determine the minimum volume of cases needed for public reporting and make the analyses public, provide clear information about how data will be presented to the public, and provide information on the process to dispute publicly accessible data.

Response: We thank the commenter for their comments. We interpret the term ''dry run'' to reference the dry run provision in the Blueprint for the CMS Measures Management System, used in the first use of a measure in a CMS program or first results reporting.[509] We do not believe a dry run before the start of public reporting is necessary and have determined that the eCQM data are accurate enough to begin reporting. In addition, hospitals would have the opportunity to preview their eCQM data before they are made public, as required by section 1886(n)(4)(B) the Act, during a 30-day preview period.

We thank commenters for their recommendations to conduct measure reliability analyses to determine the minimum number of cases needed for public reporting. Validation of CY 2017 and CY 2018 data has shown that a majority of eCQM data was reported with agreement rates of 80 percent or higher. We refer readers to section VIII.A.10 of this final rule where this is discussed in more detail.

Comment: Several commenters opposed publishing eCQM data on *Hospital Compare* citing concerns about data context as it pertains to safety net hospitals.

Response: We thank commenters for their feedback concerning the eCQM data as it pertains to safety net hospitals. We plan to monitor the initiation of public reporting of eCQM data and welcome continued feedback from all stakeholders through webinars, listservs, and help desk questions. We will continue to monitor trends in performance, including that of safety net hospitals.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly reporting eCQM data submitted by eligible hospitals and CAHs for the Promoting Interoperability Program, beginning with the eCQM data reported for the CY 2021 reporting period and for subsequent years, and we expect to begin publicly reporting the data in the Fall of CY 2022. Hospitals will have the opportunity to review their eCQM data before it is made public, as required by section 1886(n)(4)(B) of the Act, during a 30-day preview period.

7. Technical Corrections to the Regulations

a. Corrections to Regulations for Puerto Rico Eligible Hospitals Participating in the Medicare Promoting Interoperability Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41673 and 41674), we amended § 495.104(c)(5) to specify transition factors under section 1886(n)(2)(E)(i) of the Act for the

[509] See Blueprint for CMS Measures Management System, *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

incentive payments for Puerto Rico eligible hospitals. Although our preamble discussion of the transition factors was accurate (83 FR 41673 and 41674), our amendments to the regulation text included inadvertent technical errors. Specifically, under § 495.104(c)(5)(viii), we inadvertently included FY 2018 twice and omitted FY 2021 (83 FR 41710 and 41711). We proposed to correct these errors in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32857) by revising § 495.104(c)(5)(viii) to specify the correct transition factors for FYs 2018 through 2021 as follows:

- 1 for FY 2018.
- 3/4 for FY 2019.
- 1/2 for FY 2020.
- 1/4 for FY 2021.

b. Corrections to Regulatory Citations

In prior rulemaking, we adopted regulatory text at § 495.20 which cross-references ONC's certification criteria under 45 CFR 170.314. We recently identified two typographical errors in § 495.20: specifically, paragraphs (e)(5)(iii) and (l)(11)(ii)(C)(*1*) should have cross-referenced provisions of 45 CFR 170.314, but instead certain numbers were inadvertently transposed in the cross-references. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32857 through 32858), we proposed to revise §§ 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) to correct these errors.

We received no comments on these proposals and are finalizing the proposed revisions to § 495.104(c)(5)(viii) and §§ 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) as proposed.

8. Future Direction of the Medicare Promoting Interoperability Program

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32858), we solicited public comment on several areas involving the Promoting Interoperability Program. This included reducing administrative burden, supporting continued alignment with the Quality Payment Program, supporting alignment with the 21st Century Cures Act final rule, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. We also solicited public comment on potential areas of overlap including: information blocking, transitioning from the Common Clinical Data Set (CCDS) to the United States Core Data for Interoperability (USCDI), finalization of a new certification criterion for a standards-based API using FHIR, and other updates to 2015 Edition health IT certification criteria and the ONC Health IT Certification Program. In maintaining our focus on how promoting interoperability, alignment, and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery, we further solicited comment on how Medicare can best support these areas of overlap.

Although we are not summarizing and responding to the comments we received in this final rule, we would like to bring attention to ONC's 21st Century Cures Act final rule (85 FR 25642 through 25961), specifically, the finalized updates to the 2015 Edition certification criteria and the ONC Certification Program. As these updates impact certification criteria referenced in the CEHRT definitions for the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, we proposed to align with these updates in the CY 2021 PFS proposed rule (85 FR 50265 through 50272), where we invite our readers to review and provide public comment.

We would like to thank commenters for the feedback, support, and responses we have received. We will continue to take all feedback into account as we develop future policies for the Promoting Interoperability Program.

IX. Changes for Hospitals and Other Providers

A. Changes in the Submission of Electronic Patient Records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs)

1. Background

CMS' Quality Improvement Organization (QIO) Program is part of the HHS' national quality strategy for providing quality and patient centered care to Medicare beneficiaries. The mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. We identify the core functions of the QIO Program as: (1) Improving quality of care for beneficiaries; (2) protecting the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and (3) protecting beneficiaries by expeditiously addressing individual concerns (such as beneficiary complaints, provider-based notice appeals, violations of the Emergency Medical Treatment and Labor Act (EMTALA), and other related responsibilities). The QIO Program is an important resource in our effort to improve quality and efficiency of care for Medicare beneficiaries.

A QIO is an organization comprised of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare. QIOs work under the direction of CMS, to improve the quality of healthcare for all Medicare beneficiaries, and to support the Medicare program.

Current law authorizes the QIOs to have access to the records of providers, suppliers, and practitioners under Medicare in order to perform their functions. For example, section 1154(a)(7)(C) of the Act requires QIOs, to the extent necessary and appropriate, to examine the pertinent records of any practitioner or provider of health care services that is providing services for which payment may be made under the Medicare program. Section 1156(a)(3) of the Act requires that any person who provides health care services payable under Medicare assure that services or items ordered or provided are supported by evidence of the medical necessity and quality as may reasonably be required by a reviewing QIO in the exercise of its responsibilities. Our regulations at 42 CFR 476.78(b) provide that health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO reviews. Under 42 CFR 476.78(b)(2), providers (defined broadly to include any health care facility, institution, or organization involved in the delivery of Medicare-covered services) and practitioners (defined broadly to include an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients) must provide patient care data and other pertinent data to the QIO when the QIO is collecting review information. In practice, this typically includes providing the QIO with copies of medical records for Medicare beneficiaries. In addition, under 42 CFR 480.111, QIOs are authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the QIO area; QIOs may require the institution or practitioner to provide copies of such records or information to the QIO. In some cases, this access to information may include information from the records of non-Medicare patients.

While § 480.111 does not explicitly require submission of electronic patient

records, the current regulation at § 476.78(b)(2)(ii) requires providers and practitioners to send patient records in electronic format, if available, and subject to the QIO's ability to support receipt and transmission of the electronic version of patient records. The changes included in this final rule will make electronic submission the default method of submission, mandating all providers and practitioners who provide patient records to the QIO to submit them in electronic format unless they have an approved waiver. Providers and practitioners would be required to deliver patient records within 14 calendar days of a request. We believe the QIOs have developed the capability to securely receive and transmit medical patient records in electronic format, such that requiring submission of requested patient records in electronic format by providers and practitioners who has the capability is now reasonable. This is demonstrated by the fact that QIOs currently submit case files and patient records to the Departmental Appeals Board (DAB) and the Office of Medicare Hearings and Appeals (OMHA) electronically. Based on these facts, it is now evident that all QIOs are able and capable of receiving and sending patient records in electronic format.

In 2011, we established the Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability programs) to encourage eligible professionals, eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT). Beginning in 2019, all eligible professionals, eligible hospitals, and CAHs are required to use CEHRT to meet the requirements of the Medicare and Medicaid Promoting Interoperability Programs. Requirements for eligible hospitals, and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program were updated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677). Based on the National Center for Health Statistics' 2017 National Electronic Health Records Survey, 97 percent of hospitals and 80 percent of office based physicians have adopted certified EHRs. The use of certified EHRs would enable healthcare providers to electronically submit patientrecords to the QIOs. See: *https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm.*

In § 476.1, ''provider'' is defined as a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act. The term ''practitioner'' means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients. The regulations define ''QIO review'' as a review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors. The definitions specific to 42 CFR part 480 do not explicitly define the terms institution or practitioner but the context makes it clear that these terms are references to health care providers that are facilities and individual practitioners. The changes we are implementing in this final rule address submissions of patient records by all types of health care providers to QIOs and reimbursement for those submissions.

2. Changes

In this final rule, we amend §§ 412.115, 413.355, 476.78, 480.111, and 484.265 to mandate providers and practitioners submit patient records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs) in an electronic format. This proposal would also update the procedures and reimbursement rates for patient records providers and practitioners furnish to QIOs. We define the term ''patient record'' at § 476.78(e)(1) as all patient care data and other pertinent data or information relating to care or services provided to an individual patient, in the possession of the provider or practitioner, as requested by a BFCC–QIO for the purpose of performing one or more QIO functions. Providers in this context would include an institution. As discussed in more detail later in this section, we understand that QIOs request and receive primarily (if not only) records and information that is about or related to the health care provided to specific individuals. This broad definition would include any information relevant or pertinent to a particular individual (or services or Medicare-covered benefits provided to an individual) that is requested by a QIO is part of the patient record for that individual, even if the information is not necessarily part of what is traditionally understood as a medical record. We received no public comment on this definition of the term ''patient record'' and how we use the term defined this way as the basis for reimbursement for submission of electronic patient records.

Under section 1866(a)(1)(F) of the Act, CMS is required to reimburse hospitals for the cost of providing patient records to the QIOs for QIO functions as discussed in this final rule. Based on similar requirements applicable to other providers and the history of litigation related to this provision, we subsequently applied this requirement to additional providers and suppliers under Medicare. The provisions governing reimbursement for sending patient records to the QIOs is codified at 42 CFR 476.78 and 42 CFR 480.111. In this final rule, we are finalizing the following changes to the reimbursement requirements:

- Patient records that are required to be provided to a QIO under § 476.78(b)(2) must be delivered in electronic format, unless a QIO approves a waiver. Providers and practitioners who lack the capability to submit patient records in an electronic format may only submit patient records by facsimile or photocopying and mailing, after the QIO approves a waiver. Initial waiver requests by those providers that are required to execute a written agreement with a QIO are expected to be made at the time the provider executes a written agreement with the QIO. Other providers and practitioners who are not required to execute a written agreement with a QIO may request a waiver by giving the QIO notice of their lack of capability to submit patient records in electronic format.
- We establish reimbursement rates of $3.00 per patient record that is submitted to the QIO in electronic format and $0.15 per page for requested patient records submitted by facsimile or by photocopying and mailing (plus the cost of first class postage for mailed photocopies), after a waiver is approved by the QIO.
- We establish that these reimbursement rates are applicable to patient records submitted to a QIO in accordance with §§ 412.115, 413.355, 476.78, 480.111, and 484.265.

We believe these changes bring the procedures and associated reimbursement rates for submission of patient records to a QIO up to date with CMS policies for promoting use of electronic health records and burden reduction.

These changes are applicable to all providers and practitioners providing patient records to QIOs for purpose of QIO reviews under § 476.78. In addition, these requirements are applicable to institutions and practitioners submitting records and information to the QIOs in accordance with § 480.111. Specifically, such

institutions and practitioners must conform with the requirement applicable to providers and practitioners under § 476.78(c) and (d). By the cross-references in the amended regulation text, we permit reimbursement by the QIOs to institutions and practitioners for providing records and information to the QIOs under § 480.111 using the same manner and rates as would apply to providers and practitioners under § 476.78(e). To align with these and other changes, we also amend other regulations that address submitting patient records for QIO reviews, specifically: §§ 412.115, 413.355, and 484.265. We address these changes individually in this section of the document.

We proposed in §§ 412.115(c), 413.355, and 484.265 to revise the current text which provides for an additional payment to be made, respectively, to hospitals, skilled nursing facilities and home health agencies in accordance with § 476.78 for the costs of photocopying and mailing medical records requested by a QIO. Specifically, we proposed to revise these provisions to permit an additional payment to a hospital, skilled nursing facility, or home health agency in accordance with § 476.78 for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing. These changes ensure that reimbursement is permitted for all healthcare providers and practitioners, on the same basis and at the same rates as authorized for the submission of requested patient records to the QIO under our proposed revisions to § 476.78.

The previously adopted regulation at § 476.78(c) described a photocopying reimbursement methodology for prospective payment system providers and included a step-by-step analysis of how CMS calculates provider costs of photocopying. We believe that including this description of how CMS determines a rate for reimbursement for photocopying patient records is no longer necessary in light of changes in technology and procedure, and proposed to remove the step-by-step analysis from § 476.78(c). We expect that up to 20 percent of providers will seek waivers allowing them to submit patient records by facsimile or photocopying and mailing if CMS authorizes reimbursement for the submission of patient records in an electronic format, and that that number would decrease further over time. This estimate of the number of affected entities that will submit waiver requests is based on the fact that according to the 2017 Office of National Coordinator (ONC) and Center for Disease Control (CDC) provider and practitioner survey of EHR adoption and use of Certified EHR technology, 99 percent of hospitals and 76 percent of office based clinicians have adopted certified EHR technology. See: *https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm.*

This assumption is further supported by the number of providers that currently have access to CMS's esMD portal, which eliminates the need for healthcare providers to submit medical documentation to CMS's medical review contractors (such as QIOs and Regional Audit Contractors) by facsimile or photocopying and mailing. Therefore, we expect that future updates to the calculation of photocopying reimbursement rate would be of decreasing concern to the majority of stakeholders.

At § 476.78(c), we proposed that information that is required to be delivered to a QIO by a provider or a practitioner under § 476.78 must be delivered in an electronic format using a mechanism specified by the requesting QIO. We proposed that in the absence of a mechanism specified by the requesting QIO, the requested records may be submitted using any CMS approved secure mechanism. This includes mechanisms such as: secure file transfer (SFT), managed file transfer (MTF), Electronic Submission of Medical Documentation System (esMD), or CMS-approved internet portal, or CMS-approved physical medium for submitting electronic records. Under our proposal, CMS will provide a list of approved mechanisms for submission of records and information to the QIO in an electronic format when the QIO contacts the provider to conduct a review, or when a written agreement between the QIO and provider is executed. We proposed to address the amount of reimbursement in new paragraph (e) of § 476.78, as discussed later in this section. CMS would not permit the QIOs to reimburse for any patient record submitted by facsimile or by photocopying and mailing, if the provider or practitioner in question does not have an approved waiver.

We proposed to redesignate existing § 476.78(d) as § 476.78(f), with revisions to be consistent with our proposed reimbursement rates. We proposed to create a new provision at § 476.78(d) to establish a process for practitioners and providers to request waivers of the requirements for the electronic submission of requested patient records to the QIOs under proposed § 476.78(c). A QIO-approved waiver would afford a provider or practitioner who is not capable of submitting patient records to its QIO in an electronic format the opportunity to continue submitting patient records using facsimile or by photocopying and mailing. We proposed that providers who are required to execute a written agreement with a QIO, but which lack the capability to submit requested patient records in electronic format to the requesting QIO, must request a waiver of the requirement to submit records in an electronic format to the QIO. A request for a waiver by providers who are required to execute a written agreement with the QIO, must generally be made to the QIO when executing a written agreement with the QIO. However, where such a provider's lack of capability arises after the written agreement is executed, we proposed that the provider could request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format. We also proposed, at § 476.78(d)(2)(ii), that the waiver would become part of the written agreement between the QIO and the provider. Upon approval of a waiver, a provider or practitioner may submit requested patient records by facsimile or photocopying and mailing. We note that the current regulations do not specifically provide for reimbursement for patient records submitted to the QIO by facsimile, but in order to encourage efficiency in patient record transmission, CMS has historically interpreted the provisions governing reimbursement for patient records submitted to the QIOs through photocopying and mailing to also authorize reimbursement for the submission of patient records by facsimile. We proposed to specifically incorporate our historic interpretation into the regulatory framework. We solicited comment on these proposals, including the requirement that the request for a waiver must generally be made during execution of the written agreement.

Similarly, we proposed that providers, practitioners and institutions subject to § 476.78 or § 480.111 that are not required to execute a written agreement with the QIO, may also request a waiver of the requirement to submit records in electronic format to the QIO, by notifying the QIO that they lack the capability to submit patient records in an electronic format. Upon approval of the waiver, a provider or practitioner may submit requested patient records and information by photocopying and mailing. We solicited comment on this proposal, including

whether the regulation should require a written record of the waiver.

We proposed to establish these waiver processes because we recognize that some practitioners and providers may lack the capacity to submit records to the QIOs in an electronic format. However, these providers and practitioners are still required to comply with QIO requests for records. We believe the waiver request process would not add extra burden on the providers and practitioners because they can request a waiver simply by notifying the QIO that they lack the capability to submit patient records in an electronic format, either when executing a written agreement with the QIO in accordance with § 476.78(a) or when they are contacted by the QIO to request patient records. Under our proposal, such waiver requests could be made by whatever means the provider or practitioner uses to communicate with the QIO. We invited comment on these proposals.

We also proposed to add a new paragraph (e) to § 476.78. In § 476.78(e)(1), we proposed a definition of the term ''patient record'' for purposes of reimbursement for submitting patient records to the QIO for one or more QIO functions. In § 476.78(e)(2), we proposed to authorize QIOs to reimburse providers and practitioners for submitting patient records, requested by a QIO for the purpose of carrying out one or more QIO functions with the proposed rates of reimbursement based on the electronic format of submission. The QIOs could not reimburse for any patient record submitted by facsimile or by photocopying and mailing without an approved waiver. Each of these reimbursement rates were calculated to reflect the costs associated with submitting a patient record, including labor and supplies. Proposed § 476.78(e)(2) would provide that a QIO could reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per record. We proposed that § 476.78(e)(3) will provide that a QIO may reimburse a provider or practitioner, with an approved waiver in place, for requested patient records submitted by facsimile or photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage for patient records submitted via photocopying and mailing. We discuss the methodology, we proposed to use to calculate these payment rates in section IX.A.2.b. of the preamble of this final rule.

For purposes of QIO reimbursement under § 476.78(e), we proposed to define a ''patient record'' at § 476.78(e)(1) as all patient care data and any other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO, for the purpose of performing one or more QIO functions. We proposed to interpret and use this definition of patient record broadly. For example, this definition of ''patient record'' would include the policies and established operating procedures of a health care provider, to the extent that that information is pertinent to an individual patient or the services or Medicare-covered benefits provided to an individual patient, and the QIO requests that information. We also proposed at § 476.78(e)(4) that the QIOs will only be permitted to reimburse a practitioner or providers once for each patient record submitted, for each request made by a QIO. Each request from a QIO would be reimbursed separately at the rates specified in § 476.78(e), including for records that had already been provided in response to a previous request. However, only one reimbursement would be provided by the QIO for each patient record submitted, per request, even if a particular patient record is submitted to the QIO using multiple different formats, in fragments, or more than once in response to a particular request.

We proposed to revise the requirements applicable to institutions and practitioners submitting records and information to the QIOs in accordance with § 480.111. Specifically, we proposed to require such institutions and practitioners to conform with the requirement applicable to providers and practitioners under § 476.78(c) and (d). By the cross-references in the regulation text, we proposed to permit reimbursement by the QIOs to institutions and practitioners for providing records and information to the QIOs under § 480.111 in the same manner and rates as would apply to providers and practitioners under proposed § 476.78(e). In our proposal, the reimbursement rates proposed under § 476.78(e) will also apply to institutions and practitioners subject to § 480.111. We proposed to replace the current language in§ 480.111(d) governing the reimbursement by the QIO for requested patient records with a provision that refers to the reimbursement rates in § 476.78(e).

Therefore, if these changes are finalized, reimbursement for patient records submitted under § 480.111 would be consistent with reimbursement under § 476.78. This proposal would provide a consistent level of reimbursement from submission of patient records to the QIOs, across all health care providers and practitioners, that submit patient records to the QIO under §§ 476.78 and 480.111. The goal of our proposal was to put all QIO reimbursement for patient records in the same section of the regulations, so that QIOs, providers, and practitioners know where to find the relevant provisions. This proposal would also help to reduce the risk of inconsistencies in policy application due to duplication of related QIO regulations in multiple sections.

We received no comments on the definition of the term ''patient record'' for purposes of reimbursement by a QIO at 476.78 (e)(1) when submitted for one or more required QIO activities; the requirement for QIOs to reimburse providers and practitioners once per request for the submission of a patient record at 476.78 (e)(4). We are finalizing these changes as proposed without modification.

We proposed redesignating the existing provisions previously under § 476.78 (d) to a new paragraph: § 476.78(f). We proposed revisions to the text of proposed redesignated § 476.78(f) to provide greater consistency with our proposed reimbursement requirements; the proposed revisions to § 476.78(b)(2)(ii) to make electronic submission the default method of submission and mandate that all providers and practitioners who provide patient records to the QIO to submit them in electronic format within 14 calendar days of a request, unless they have an approved waiver. In addition, the requirements for submitting patient records to the QIO in an electronic format unless they obtain an approved waiver from the QIO and the ability for the QIO to reimburse providers for electronic submission of patient records are applicable to all providers and practitioners under §§ 412.115, 413.355; 476.78, 480.111, and 484.265. Accordingly, we are finalizing these provisions as proposed, without modification.

a. Required Submission of Patient Records in Electronic Format to the QIO, and Process for Obtaining a Waiver From Required Submission in Electronic Format

Currently § 476.78 requires providers and practitioners who are subject to QIO review activities under 42 CFR part 476 to submit requested patient care data and other pertinent data and information to the QIO. We proposed to require those submissions be made in electronic format in revised § 476.78(c).

We proposed to require electronic submission because it is more efficient, cost effective, and timely. Based on our comparison of patient record submission in electronic format and submission by facsimile and photocopying and mailing we expect a savings of about $71.8 million to CMS over 5 years. These savings represent an estimated combination of $37.6 million cost savings from reimbursement to providers for sending patient records via facsimile, photocopying and mailing, and $34.2 million cost saving from payment to QIOs to cover the costs for scanning and uploading paper based patient records.

Currently, § 476.78(b)(2)(ii) requires providers and practitioners send secure transmission of an electronic version of medical information to the QIO, if available, and subject to the QIO's ability to support receipt and transmission of the electronic version of patient records. Because most providers and all QIOs have demonstrated the ability to send and receive patient records in electronic format, we proposed to mandate providers and practitioners to submit requested patient records and information to the QIO in electronic format.

Our interoperability programs, quality reporting programs, and other programs are now requiring electronic submission of patient care data and information to CMS and its contractors. The Promoting Interoperability program has been successful in encouraging widespread adoption of EHRs by providers and practitioners. By participation in these CMS data transfer programs, providers, practitioners, and QIOs have demonstrated the capability to collect, store, and safely transmit EHR data electronically. Based on our years of experience administering the Medicare and Medicaid EHR Incentive and Promoting Interoperability programs, we believe that most providers and practitioners are now able to safely communicate patient's medical records electronically to QIOs. This is evidenced by the increased number of providers, practitioners, and QIOs that currently participate in the use of esMD, Managed File Transfer (MFT), and other related electronic data communication methods.

On September 15, 2011, we implemented the esMD system for programs requiring the review of medical documentation and patient records such as: Medicare Fee for service payment appeals, prior authorization requests, and durable medical equipment requests. The esMD system is used by providers on a voluntary basis to transmit medical documentation to review contractors electronically. This medical documentation (including patient records) is used by CMS contractors to review claims and to verify providers' compliance with Medicare rules for documentation and payment. Medicare providers and review contractors believe that using the esMD system results in cost savings and increased efficiencies, as well as improve payment turnaround time, and reduce the administrative burden associated with medical documentation requests and responses. By 2017, about 60,579 providers had access and used esMD to send medical records, and up to 2.5 million medical records were transmitted from providers to Medicare contractors. See 2017 esMD Annual Report: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/Downloads/2017-esMD-Annual-Program-Report-10-01-2016-09-30-2017.pdf*.

Managed File Transfer (MFT) refers to a software or a service that manages the secure transfer of data from one computer to another through a network (for example, the internet). MFT software is marketed to corporate enterprises as an alternative to using ad-hoc file transfer solutions. MFT is currently available to providers and practitioners, and QIOs currently use MFT to transmit data to its clinical peer reviewers. MFT provides another good option for providers and practitioners to submit records and information securely to QIOs.

Given numerous improvements in electronic data communication capabilities among both providers and QIOs, and the expansion in access to electronic data communication technology, we believe it is in the best interest of the Medicare program for CMS to support electronic data communication between the QIOs and providers and practitioners. We proposed to require providers and practitioners to provide patient records to the QIO electronically beginning in FY 2021 and for subsequent years. Our proposal provided for a waiver for providers and practitioners that lack the capability to submit patient records in electronic format. Lacking the capability to submit patient records in electronic format may have a number of causes, such as the records not being in an electronic format or readily convertible to an electronic format or the provider or practitioner suffering a loss of the necessary resources to submit records through the QIO-approved or CMS-approved mechanism (such as because of a power outage). The intent of this policy change is to incentivize health care providers and practitioners subject to § 476.78 to use the most efficient mechanisms available to submit required data to the QIOs for review activities, in order to minimize the time and expense required to satisfy their responsibilities under § 476.78(b), and thereby minimize the expense CMS incurs in the administering the QIO program. A complete discussion of the anticipated impact of these proposals can be found section I.H.11. of Appendix A to this final rule.

We received no comments on our proposal to require providers and practitioners to submit patient records in an electronic format under § 476.78 (c) unless they have an approved waiver from a QIO pursuant to § 476.78(d); the process for providers and practitioners to obtain a waiver from the requirement to submit patient records to the QIO in an electronic format under § 476.78(d); and the applicability of these requirements to providers practitioners and institutions under §§ 412.115, 413.355; 476.78, 480.111, and 484.265.

We proposed to permit providers and practitioners who cannot submit requested patient records and information in electronic format to request a waiver under § 476.78(d). Under our proposal, any provider or practitioner that lacks the capability to submit patient records and information to the QIO in electronic format must obtain a waiver to be exempted from the requirement of submitting patient records and information in electronic format. Upon approval of the waiver, the provider or practitioner can submit requested patient records and information to QIO by facsimile or first class mail. We also proposed that requests for waivers by providers that are required to execute a written agreement with the QIO must generally be made to the QIO when executing the written agreement. Those providers and practitioners that are *not* required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in electronic format by notifying the QIO that they lack the capability to submit patient records in electronic format.

After the waiver is approved a provider or practitioner may send requested patient records and information by facsimile or first class mail. The QIOs may reimburse providers and practitioners with approved waivers for requested patient records submitted by facsimile or by photocopying and mailing, as proposed in § 476.78(e)(3). We proposed that a waiver would be approved by the QIO after the provider or practitioner has

demonstrated that it lacks the capability to submit patient records in an electronic format. Under our proposal, reimbursement would not be permitted for any patient record submitted to the QIO by facsimile or by photocopying and mailing, when the provider or practitioner does not have an approved waiver.

We received no comments on the proposed waiver process at § 476.78(d) for exempting providers and practitioners from the requirement to submit patient records to the QIO in an electronic format, or on limiting reimbursement of providers and practitioners under § 476.78(e)(3) for the submission of patient records to the QIO through photocopying and mailing or by facsimile to circumstances in which a provider or practitioner has obtained an approved waiver from the electronic submission requirements under § 476.78(d). As a result, we are finalizing the proposed changes at § 476.78(d) and § 476.78(e)(3) without modification.

b. Reimbursement for Submission of Patient Records to the QIOs in Electronic Format

We proposed at § 476.78(e)(2) to authorize the QIOs to reimburse providers and practitioners, for submitting requested patient records to the QIO in an electronic format, starting in FY 2021. The regulation previously did not authorize or set a rate for reimbursement when providers submit patient records to the QIOs in an electronic format. We believe the lack of reimbursement for the submission of requested patient records in an electronic format discouraged providers and practitioners from sending patient records in an electronic format, which is a more efficient and cost effective method for transmitting patient records than facsimile or photocopying and mailing. This lack of reimbursement for electronic submission of patient records did not align with other CMS programs and policies that seek to incentivize the use of electronic records and the electronic transmission of information such as the Promoting Interoperability Program. We believe this change in regulation, allowing QIOs to reimburse providers and practitioners for submitting patient records in electronic format, would encourage more practitioners and providers to do so.

In calculating the rate of reimbursement for submission of patient records in an electronic format, we took into consideration the labor rate and materials cost associated with submitting patient records in an electronic format. We proposed to follow steps similar to those used in CMS' methodology for calculating reimbursement for photocopying patient records for the QIOs. We calculated the proposed reimbursement rate for patient records submitted in electronic format as follows:

- *Step 1*—Calculate total salary of a medical records clerk, including fringe benefits, using the salary level for an experienced midlevel (GS–5 step 5) secretary in the Federal government as representative of that of a medical records clerk.
- *Step 2*—Calculate labor costs associated with searching for, downloading, and submitting electronic records.
- *Step 3*—Determine the number of patient records that can be searched, retrieved, processed, and submitted per hour.
- *Step 4*—Calculate the cost of active productive time of a medical record clerk by dividing annual salary with total productive hours, taking into account time spent at rest, and away from work.
- *Step 5*—Calculate total reimbursement for submitting patient records to the QIOs in electronic format by dividing the total productive hour cost by the total number of patient records we estimate a medical records clerk can process in 1 hour.

Using this methodology, we calculated the reimbursement for submitting records electronically to QIO as follows:

(1) The Labor Costs Associated With Searching for, Downloading, and Submitting Patient Records

Labor costs were calculated by adding the annual salary of a medical records clerk with the costs of fringe benefits, and dividing that sum with the number of patient records that can reasonably be expected to be processed in a year.

In this final rule, we will continue to use the salary of a Federal GS–5 midlevel secretary as representative of a medical records clerk's salary. We will take into account increases in the payment rate for a midlevel secretary in the federal government for the CY 2020. Using the salary level for an experienced midlevel (GS–5 step 5) secretary in the Federal government as representative of that of a medical records clerk, the annual salary of the medical records clerk is estimated to be $39,573 according to the Office of Personnel Management's 2020 General Schedule pay scale, with locality adjustment for the rest of the United States. In calculating the fringe benefits applicable to a medical records clerk, we used OMB Circular A–76 to calculate the annual fringe benefit cost, based on 36.25 percent of the GS–5 salary. The estimated annual fringe benefit cost is therefore $14,345 ($39,573 * 36.25 percent). Adding the fringe benefit cost, the estimated total annual salary of a medical records clerk is $53,918. Assuming a full time equivalent of 2080 hours per year and divide the annual salary by the number of hours worked ($53,918/2080 hours) in a year, the total salary per hour of a medical records clerk would be $26 per hour.

(2) Labor Costs Associated With Searching for, Downloading, and Submitting Patient Records

We assume that an average patient record request by QIO will be contained in a single electronic file that can be classified as one electronic record. This assumption is based on CMS' experience with current QIO transfer of electronic patient records to OMHA and the DAB. We estimated that it will take a medical record clerk an average of 5 minutes to search, retrieve, process, and submit a requested patient record in electronic format. Using this estimate we calculate that a medical records clerk could search for, retrieve, process, and submitted a total of 12 medical records per hour.

(3) Active Productive Time of a Medical Record Clerk

We estimate a medical records clerk is active and productive for a total of 1,430 hours per year (about 5.5 productive hours per day). We took into account the time spent by the medical records clerk at rest and lunch, and time away from work on annual vacation, sick, and holiday leave. To calculate the cost of one active productive hour we divide the estimated cost for annual salary and fringe benefits by the total number of active productive hours per year. We estimated the cost of one active productive hour at $38 per hour ($53,918/1430 hours).

(4) Cost of Supplies

We estimated that there would be no cost for supplies directly attributable to searching, downloading, and submitting patient records to the QIO.

(5) Total Reimbursement Rate for Submitting Patient Records to the QIOs in an Electronic Format

We estimated total cost for submitting a patient record to the QIO at $3 per record. This calculation was derived by dividing the total productive hour cost of $38 by the number of patient records that can processed in an hour, which is 12 records ($38/12 records = 3.17).

Consistent with our policy and generally accepted mathematics principles, we chose to round our calculations to nearest decimal. We believe this decision is both reasonable and supportable.

We invited public comment on this proposed methodology for calculating the rate of reimbursement for processing patient records in an electronic format. In addition, we invited public comment on alternative methodologies for determining more appropriate reimbursement rate for the submission of patient records to the QIOs in an electronic format, and we intend to finalize our policy in this final rule based upon the public comments received.

We received no comments regarding our proposals under § 476.78(e)(2) to allow QIOs to reimburse providers or practitioners for the electronic submission of patient records, or the methodology or content used to calculate the $3.00 reimbursement rate for the electronic submission of patient records. Therefore we are finalizing our proposals for the regulation at § 476.78(e)(2) allowing QIOs to reimburse providers and practitioners at a flat rate of $3.00 per requested patient record as proposed and without modification.

c. Reimbursement Rate for Providers Submitting Patient Records by Photocopying and Mailing

We proposed that the QIOs would reimburse providers with approved waivers for submitting patient record by photocopying and mailing. We proposed at § 476.78(e)(3) to increase the reimbursement rate for submitting patient records by photocopying and mailing from $0.12 per page to $0.15 per page. We are updating this payment rate in accordance with CMS's commitment to periodically revise the photocopying reimbursement rate. This rate adjustment is fair, reasonable, and meets the current labor and material cost articulated in the established formula for calculating photocopying reimbursement rate. We proposed to use the following formula for updating the rate of reimbursement for photocopying and mailing records to QIO as follows:

- *Step 1.* CMS adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB circular A–76, to establish a total annual salary for the photocopy machine operator.
- *Step 2.* CMS divides the total annual salary of the photocopy machine operator by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.
- *Step 3.* CMS adds to the per-page labor cost as previously determined in step two to the per-page costs of photocopying supplies.

We used this methodology to determine what specific rate to propose for the reimbursement for sending patient records by photocopying and mailing patient records. We proposed to increase the per-page reimbursement rate to $0.15 for photocopying patient records. We calculated the proposed photocopying reimbursement rate by updating the salary, fringe benefits, and supply figures associated with photocopying and submitting patient records to the QIO. In accordance with this methodology we considered the following factors in calculating the proposed new rate:

(1) Labor Costs Associated With Photocopying and Submitting Patient Records

Labor costs for photocopying patient records were calculated by adding the annual salary of a photocopy machine operator with the costs of fringe benefits, and dividing that sum by the number of pages that can reasonably be expected to be photocopied in 1 year. We proposed to continue to rely upon the salary of a Federal GS–5 midlevel secretary as representative of a photocopy machine operator's salary. Using the salary level for an experienced (GS–5) midlevel secretary in the Federal government as representative of that of a photocopy machine operator, the annual salary of the photocopy machine operator is estimated to be $39,573, according to the Office of Personnel Management's 2020 General Schedule pay scale. This estimate included the locality pay adjustment for the rest of the United States. In calculating the fringe benefit of we used OMB Circular A–76 to calculate the annual fringe benefit cost, based on 36.25 percent of the GS–5 salary. The annual fringe benefit cost is $14,345 ($39,573 * 36.25 percent). Adding the fringe benefit, the estimated total annual salary of the photocopying operator is estimated at: $53,918. To determine the per-page labor cost, the total of salary ($39,573) and fringe benefits ($14,345) costs, which amount to $53,918, was divided by 624,000 pages, the number of photocopies a photocopy machine operator can make in 1 year. The estimated labor cost for photocopying 1 page of patient records is $0.08 ($53,918/624,000 pages).

(2) Number of Pages a Photocopy Machine Operator Can Photocopy Annually

We estimated the total number of pages that a photocopy machine operator can photocopy per year based on hand feeding of documents into a photocopying machine. We recognize that modern technologies exist which support faster photocopying, such as through automatic paper feeds. We are aware that using an automatic paper feeds can greatly increase the number of pages that can be photocopied per minutes, and as a result, greatly decrease the cost of photocopying per page. We assume that not all providers and practitioners has access to modern technology or uses modern photocopier capable of automatic paper feed. Therefore, we would calculate the number of page a photocopy machine operator can photocopy, using the manual paper feed estimate. In calculating the number of pages that can be photocopied per hour using a manual feed, we took into consideration that recent improvements in photocopying machine technology has improved the speed of photocopier up to 8 pages per minute. In order to account for time spent by the photocopy machine operator in search and retrieval tasks, and time away from work on annual vacation, sick, and holiday leave, the total number of work hours per year is estimated at 1,300 (an average of 5 productive hours per day), resulting in a total of 624,000 (1,300 hour × 60 minutes × 8 pages) pages per year.

(3) Costs of Photocopying Materials and Supplies

We proposed a total estimated supply cost of $0.07 per page, based on a per-page paper cost of $0.06 and a per-page toner and developer cost of $0.01 per page. The supply cost include the cost of photocopying paper and toner cartridge. Using the market survey cost for these materials we estimated the average cost, using the average price and quality at the GSA material supplies rate, we estimated that copier paper cost of $0.06 per page for paper and $0.01 per page for photocopy machine toner. The paper cost was based on a cost of $32.49 per case for recycled white photocopier paper of 5,000 sheets in a case. The costs of photocopier toner that yield 37,000 copies was estimated at $54.99 per toner cartridge. We calculated these costs using estimates of the costs for recycled photocopier paper and toner cartridges contained in the GSA supply catalogue.

(4) Total Reimbursement Rate for Photocopying Patient Records

We estimate total cost of photocopying at $0.15 per page. This calculation was derived by adding the total estimated labor cost of $0.8 per page and total cost of photocopying supplies of $0.07 per page. Consistent with our policy and generally accepted mathematics principles, we chose to round our calculations to nearest decimal. We believe this decision is both reasonable and supportable. We invited public comment on this proposed methodology for calculation of the rate for reimbursement for sending patient records and information by photocopying. In addition, we invited public comment on alternative methodologies for determining a more appropriate photocopying reimbursement rate and intend to finalize a policy based upon the public comments received.

Comment: A commenter suggested that CMS eliminate the reimbursement for patient records submitted to QIOs by photocopying and mailing. The commenter suggested that to encourage modernization, CMS should only pay for electronic submission of patient records.

Response: We consider this comment generally supportive of the proposed change to require electronic submission of patient records to the QIO, however we disagree with the commenter's suggestion to eliminate reimbursement for patient records submitted to the QIOs via photocopying and mailing. As stated earlier in this rule, CMS believes that up to 20 percent of providers may lack the capacity to submit patient records in electronic format, and will seek a waiver from the requirement to submit electronically. CMS seeks to provide fair reimbursement to these providers and practitioners for submitting patient records as requested by a QIO for the purpose of performing one or more QIO functions via alternative modes of submission until such time as evidence indicates these alternative modes of submission are obsolete. While we are not adopting the commenter's suggestion at this time, we appreciate the feedback and will take this comment into consideration in future development of CMS's reimbursement policies and rates for patient records submitted to the QIOs.

After consideration of the public comment received, we are finalizing the updated reimbursement rate for the submission of patient records to the QIOs via photocopying and mailing, of $0.15 per page for photocopying plus first class postage for providers with approved waivers from the requirement to submit patient records in electronic format, without modification.

d. Reimbursement Rate for Providers Submitting Patient Records by Facsimile

We proposed at § 476.78(e)(3) to reimburse providers and practitioners with approved waivers that submit patient records to the QIO by facsimile at the rate of $0.15 per page. The current regulations do not specifically provide for reimbursement for patient records submitted to the QIO by facsimile, but CMS has historically interpreted the provisions governing reimbursement for patient records submitted to the QIOs through photocopying and mailing to also authorize reimbursement for the submission of patient records by facsimile. We are now proposing to specifically incorporate our historic interpretation into the regulatory framework. According to this proposal the QIOs would continue to provide for reimbursement for patient records submitted to the QIO via facsimile, using a rate estimated based on the costs associated with submitting patient records to the QIO by facsimile. We believe the rate we proposed is fair, reasonable, and reflects current labor and material costs associated with sending patient records to the QIOs by facsimile. We calculated the reimbursement for submitting patient records by facsimile to the QIO as follows:

- *Step 1.* CMS adds the annual salary of a facsimile machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB circular A–76, to establish a total annual salary for the facsimile machine operator.
- *Step 2.* CMS divides the total annual salary of the facsimile machine operator by the number of pages of patient records that can be reasonably expected to be sent annually by facsimile. This calculation establishes the labor cost per page of patient records submitted by facsimile.
- *Step 3.* CMS adds to the per-page labor cost as determined in step two to the average cost of maintaining a dedicated phone line for facsimile service.

We used this methodology to determine the specific rate of reimbursement we proposed for submitting patient records to the QIO by facsimile. Similar to our methodology for calculating a fair and appropriate reimbursement rate for submitting records to the QIO via photocopying and mailing, we calculated the proposed reimbursement rate for sending patient records to the QIO by facsimile as follows:

(1) Labor Costs Associated With Submitting Patient Records by Facsimile

Labor costs were calculated by adding the annual salary of a facsimile machine operator with the costs of fringe benefits, and dividing that sum by the number of pages that a single facsimile operator can reasonably be expected to submit in a year. We proposed to rely upon the salary of a Federal GS–5 midlevel secretary as representative of a facsimile machine operator's salary. Using the salary level for an experienced (GS–5) midlevel secretary in the Federal government as representative of that of a facsimile machine operator, the annual salary of the facsimile operator is estimated to be $39,573 according to the Office of Personnel Management's 2020 General Schedule pay scale, including the locality adjustment for the rest of the United States. In calculating the cost of fringe benefits we used OMB Circular A–76 to calculate the annual fringe benefit cost, based on 36.25 percent of the GS–5 salary. The annual estimated fringe benefit cost is $14,345 ($39,573 * 36.25 percent). With fringe benefits, we estimated total annual salary of the facsimile operator at $53,918.

(2) Number of Pages a Facsimile Operator Can Submit Annually

We estimated the total number of pages that a facsimile machine operator could submit per year based on hand feeding of documents into facsimile machine. We recognize that several modern technologies exist which support faster faxing, such as through automatic paper feeds or faxing over the internet. These technologies greatly increase the number of pages that can be submitted by facsimile on an hourly basis, and as a result, greatly decrease per page cost of submitting patient records by facsimile. However, we took into consideration the fact that not all providers and practitioners have access to the internet or modernized facsimile machines. Therefore, we proposed to calculate the per page reimbursement rate using the manual paper feed as our guide. We estimated that a facsimile machine operator using a manual feed can submit 5 pages of patient records to the QIO in 1 minute. This estimate does not account for any delay in transmission due to poor connectivity or machine fault. In order to account for time spent by the facsimile machine operator in search and retrieval tasks, and time away from work on annual vacation, sick, and holiday leave, we estimated the total number of work

hours per year at 1,300 (an average of 5 productive hours per day), resulting in a total of 390,000 (1,300 hours × 60 minutes × 5 pages) pages of patient records, which a facsimile operator can submit to the QIO in 1 year.

To determine the per-page labor cost for submitting patient records to the QIO via facsimile, we divided the total salary ($39,573) and fringe benefits ($14,345) costs, $53,918, by 390,000, the number of copies a facsimile operator can submit in a year, resulting in an estimated labor cost of $0.14 per page ($53,918/390,000 pages).

(3) Other Costs Associated With Sending Patient Records by Facsimile

We proposed to reimburse the cost of a dedicated telephone line used for a facsimile machine at the rate of $29.99 per month, for an estimated total cost of $359.88 per year. Our estimate does not take into consideration that multiple facsimile machines can use on telephone line, and that a telephone line can be used for other purposes than transmitting records via facsimile. We estimated that 1 cent per page ($359.88/390,000 pages) will reflect the cost of a dedicated telephone line used for facsimile service, based on estimated the estimated 390,000 pages of patient records we expect a facsimile machine operator could submit in a year. We estimated the cost of telephone line using the average per month cost for a single business telephone line per month based on an average drawn from comparison of major telecommunications service provider rates. We estimate that there is no reimbursable paper or material cost associated with sending patient records to the QIO by facsimile, as CMS does not reimburse providers and suppliers for the cost of machinery and overhead costs for submitting patient records to the QIOs.

(4) Reimbursement Rate for Sending Patient Records by Facsimile

We estimated the total cost of or submitting patient records by facsimile to the QIO at $0.15 per page. This estimate was calculated by adding the total estimated labor cost of $0.14 per page, and total cost of a dedicated telephone line at $0.01 per page. Consistent with our policy and generally accepted mathematics principles, we chose to round our calculations to nearest decimal. We believe this decision is both reasonable and supportable. We invited public comment on this proposed methodology for calculating the rate for reimbursement for submitting patient records by facsimile. In addition, we invited public comment on alternative methodologies for determining an appropriate facsimile reimbursement rate and intend to finalize our policy based upon the public comments received.

Comment: A commenter suggested that CMS eliminate the reimbursement for submitting patient records to QIOs via facsimile. The commenter suggested that to encourage modernization, CMS should only pay for electronic submission of patient records.

Response: We consider this comment generally supportive of the proposed change to require electronic submission of patient records to the QIO, however we disagree with the commenter's suggestion to eliminate reimbursement for patient records submitted to the QIOs via photocopying and mailing. As stated earlier in this rule, CMS believes that up to 20 percent of providers may lack the capacity to submit patient records in electronic format, and will seek a waiver from the requirement to submit electronically. CMS seeks to provide fair reimbursement to these providers and practitioners for submitting patient records as requested by a QIO for the purpose of performing one or more QIO functions via alternative modes of submission until such time as evidence indicates these alternative modes of submission are obsolete. While we are not adopting the commenter's suggestion at this time, we appreciate the feedback and will take this comment into consideration in future development of CMS's reimbursement policies and rates for patient records submitted to the QIOs.

After consideration of the public comment received, we are finalizing the updated reimbursement rate for the submission of patient records to the QIOs via facsimile of $0.15 per page for providers with approved waivers from the requirement to submit patient records in electronic format at § 476.78(e)(3), without modification.

B. Revised Regulations To Prepare for Implementation of Mandatory PRRB Electronic Filing (42 CFR Part 405, Subpart R)

1. Background

Congress created the Provider Reimbursement Review Board (PRRB or Board) in 1972 to furnish providers with an independent forum for resolving payment disputes typically arising from certain Medicare Part A final determinations (usually cost report audit appeals). (See 42 U.S.C. 1395oo and 42 CFR 405.1801 and 405.1840 through 405.1873.) The Board has the full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out its function. (See 42 U.S.C. 1395oo(e) and 42 CFR 405.1868(a).)

On average, the PRRB receives approximately 3,000 new appeals annually. The PRRB's docket is unique and complex, so it is imperative that the Board manage its docket in the most efficient manner possible. For example, an individual provider appeal may involve one or more issues; in contrast, a group appeal involves multiple providers appealing a common issue. (See 42 U.S.C. 1395oo(b) and 42 CFR 405.1837.) In addition, many providers or issues may be transferred between the cases to create a complex web of interrelated appeals. In light of these complexities, it is imperative that the Board continue to improve the efficiencies of its processes.

Until mid-2018, appeal documents (including documents such as appeal requests, transfer requests, and position papers) could only be filed with the PRRB on paper. Over the past decade, CMS and the Board have received feedback from its stakeholders requesting an electronic filing system. On August 16, 2018, the CMS Office of Hearings (OH) and the Board released the OH Case and Document Management System (OH CDMS). OH CDMS is a web-based portal where providers can file appeals and all parties can manage their cases. Besides instantaneously accepting submissions electronically, OH CDMS releases outgoing electronic correspondence and Board decisions as well. OH CDMS enables providers and their representatives to manage their cases in real time, and it allows parties to view all documents officially filed through the system (including viewing opposing parties' submissions). When a party makes a submission, whether submitting a new appeal or taking an action on an existing case, there is an immediate system notification that confirms the submission was made. All parties on the case will then receive an email confirming the date and time of delivery. Internally, the system also serves as a daily workflow management system for the PRRB and its staff and aids the PRRB in strategically managing its docket in a more efficient manner.

The feedback we have received from active users of OH CDMS has been largely positive. We have also incorporated user suggestions to refine the system. OH CDMS offers a Help Desk, available each business day, to assist users with technical questions that may arise.

2. Technical Changes To Support Electronic Filing

To support the use of the electronic filing system, we proposed technical changes throughout the regulations at 42 CFR part 405, subpart R. First, we proposed to update the definitions of ''date of receipt'' and ''reviewing entity'' at 42 CFR 405.1801(a) to indicate that submissions to an electronic filing system are considered received on the date of electronic delivery. We also proposed to add a new definition of ''in writing or written'' that indicates either of these terms means a hard copy or electronic submission. We believe these are common sense technical changes that reflect current practice and understanding. We note that we did not propose to revise the requirement in § 405.1801(a) that the date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity, including the Board, is presumed to be 5 days after the date of issuance. Therefore, regardless of whether the Board issues a decision electronically or by some other means, the 5-day presumption regarding receipt by a party would continue to apply. We also proposed technical changes throughout the subpart to replace references related to hard copy documents such as ''mail'' and ''hand delivery'' with terms that apply to both hard copy and electronic submissions. We sought comments on these changes.

We also proposed to update 42 CFR 405.1857, related to subpoenas, so that it generally conforms to the technical changes we are proposing. However, we proposed adding the following statement to this section, ''If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena must be sent by certified mail.'' This change is to ensure that the subpoena rule is in accordance with section 205(d) of the Act (Issuance of subpoenas in administrative proceedings).

3. Intention To Revise Board Instructions To Require Mandatory Electronic Submissions

As stated earlier in this preamble, the Board has the full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out its function. (See 42 U.S.C. 1395oo(e) and 42 CFR 405.1868(a).) It is critically important that the PRRB docket records be fully populated within OH CDMS so that the Board and its stakeholders can optimally realize the technological benefits and efficiencies of OH CDMS. Therefore, we are proposing to amend the regulations at 42 CFR 405.1843 (Parties to proceedings in a Board appeal) to make clear that parties to a Board appeal shall familiarize themselves with the instructions for handling a PRRB appeal, including any and all requirements related to the electronic or online filing of documents for future mandatory filing. This change to require electronic submissions would transform the PRRB's docket to a more efficient and less costly paperless environment, and will support a better continuity of operations posture. Accordingly, no earlier than FY 2021, the PRRB may require that all new submissions (in new and pending appeals) be filed electronically using OH CDMS. This requirement would be reflected in updated Board instructions, which are currently published at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/PRRB-Rules-August-29-2018.pdf*.

Because the Board plans to wait until at least FY 2021 to potentially require electronic filings, we believe that stakeholders would have ample time necessary to register and start using the system to the extent they have not already done so on a voluntary basis. Stakeholders can access the Electronic Filing web page located at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Electronic-Filing* to find instructions on accessing and using OH CDMS. We recommend that parties to PRRB appeals, who have not already, sign up for and begin using OH CDMS as soon as possible to allow time to become familiar with the system and to avoid any issues that may arise if signing up for the system is delayed until after use of the system becomes mandatory.

It has already been approximately 21 months since the system became operational and available to stakeholders. In this regard, we note the following:

- Many providers started using the system immediately after OH CDMS was launched.
- OH CDMS now has over 800 registered users, and continues to grow. We believe that this number of users is largely representative of the cohort of stakeholders that will use OH CDMS.
- Over 75 percent of all new appeals have been filed electronically by providers using the system.
- All government contractors that participate in PRRB appeals (including Medicare Administrative Contractors (MACs), the Cost Report Audit and Appeals contractor (CRAA), and the Appeals Support Contractor (ASC)) use the system.

Nevertheless, to provide additional notice to stakeholders, the PRRB would provide at least 120 calendar days' notice (through its instructions) before the exact date that electronic filing would become mandatory. Thus, under the final rule, the earliest the PRRB could publish such instructions would be October 1, 2020 and, as a result, the earliest effective date for mandatory usage of the system for PRRB appeals submissions would be November 30, 2020.

We note that making use of OH CDMS mandatory for PRRB appeals is consistent with recent revisions updating the Medicare Geographic Classification Review Board (MGCRB) regulations that similarly permit the MGCRB to require the use of OH CDMS through its instructions. The MGCRB regulatory change was published in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928 (August 22, 2016)) and the requirement to file electronically was effective for the 2020 reclassification cycle. The transition to mandatory electronic filing of MGCRB applications went smoothly, and we received positive feedback regarding OH CDMS from the user community.

Finally, we note that the provisions governing contractor hearing officer appeals, Administrative and Judicial Review and reopenings are also found in part 405 subpart R. However, we did not propose changes to the submission procedures for these processes.

Comment: We received largely positive feedback in the comments regarding OH CDMS itself, as well as support for mandatory use of OH CDMS. A commenter who has represented Providers before the PRRB for more than 35 years stated that the introduction of OH CDMS has been of substantial benefit and represents a great improvement over the hard copy filing process, and states that OH staff should be complimented on the design and implementation of the system. Another commenter applauded OH CDMS and stated that the system improves the efficient management of PRRB appeals, and that the proposed changes to the regulation are sensible and appropriate. A commenter supported the proposed changes that would allow the PRRB's adoption of rules mandating electronic filing, because OH CDMS has made it easier and quicker for providers to file and manage appeals, especially for group appeals or consolidated appeals that may include many providers and cost reporting periods.

Response: The Office of Hearings (OH) appreciates the positive feedback,

especially because OH CDMS was, in large part, created in response to the requests of parties before the PRRB to create an electronic filing system.

Comment: We received a few comments that stated that Schedules of Providers (SOP) for group appeals should be accepted in PDF format via OH CDMS, because every other document may be filed in PDF format via OH CDMS.

Response: We understand the comments regarding electronic filing of SOPs and the Board is reviewing its Instructions regarding the filing requirements for SOPs and will take this feedback into consideration.

Comment: A few commenters also stated that there should be an exception to mandatory electronic filing if a user is unable to access OH CDMS for a filing deadline due to routine maintenance of the system, technical difficulty in accessing the system, or interruption to the user's internet access. A commenter suggested that the PRRB adopt the process used by some federal district courts which allows email filings if the system is inaccessible. A commenter also stated that any day or portion of a day when OH CDMS is unavailable should not be counted for purposes of computing a deadline.

Response: We understand the concern expressed by the commenters but the nature of potential issues with electronic filing is not significantly different from those associated with hard copy filings. Accordingly, we decline to make any changes to the current regulations because we believe they provide sufficiently flexible procedural processes for the Board to address any potential filing issues (regardless of whether such issues arise with electronic filings versus hard copy filings). In this regard, we note that 42 CFR 405.1801(d)(3) provides that deadlines may be adjusted if a reviewing entity is unable to conduct business in the usual manner, which would allow the PRRB to make allowances where appropriate, *e.g.,* if OH CDMS were down for the entire last day of a deadline. Additionally, specifically with respect to timely filing of appeals, 42 CFR 405.1836 allows for good cause extension of the time limit for requesting a Board appeal, and PRRB Rule 1.6 provides for Accessibility Standards and allows for accommodations. We disagree that any day or portion of a day when OH CDMS is unavailable should not be counted for purposes of computing a deadline. We believe that while, as noted previously, exceptions to deadlines may be granted, the deadline dates should be clearly established, and shifting the deadlines for a day or portion of a day as the commenter proposes would be administratively impractical and could cause great confusion for the Board, parties, and reviewing entities alike.

Comment: A commenter noted that a provider is only allowed one representative for all appeal-related communications. The commenter was concerned that if the representative organization were to terminate that employee, electronic correspondence from the PRRB would be delivered to a dead email address and no one would actually receive the notice. The commenter requested that the PRRB monitor for ''non-delivery'' or ''out-of-office'' automated responses, so that the PRRB can send a hard copy letter to the Provider's CEO or CFO to ensure that a provider's appeal rights are not jeopardized by missed electronic communications from the PRRB.

Response: Currently, there may only be one representative per appeal and the provider's designated representative is responsible for ensuring his/her contact information is up to date and, in turn, the provider is responsible for notifying the Board of any change in its representative. Thus, it is the responsibility of the provider and/or representative to notify the PRRB if the email address is no longer valid (for example employee departure or extended leave). We believe this is a reasonable procedure and, therefore, decline to make alterations to this procedure at this time.

Comment: A commenter applauded the updates to functionality of OH CDMS that have been made since OH CDMS went live on August 16, 2018. However, some commenters also suggested the PRRB consider additional upgrades to OH CDMS, such as the functionality of ''batch uploads,'' before use of the system becomes mandatory. Users must manually enter multiple data elements for each provider, as well as separate documents that comprise each issue. The commenters believed that this process is especially time consuming for appeals that challenge rulemaking notices in the **Federal Register**, as these appeals may involve a large number of providers in a single submission and that, as a result, paper filing currently remains a distinct advantage for them for these large group submissions. A commenter suggested that being able to upload provider information as structured data would make electronic submission of large groups more feasible and reliable. A commenter requested that the OH CDMS interface be updated so that users can submit appeal in its final form, rather than in the discrete data entries.

Response: We appreciate the acknowledgement of the updates made to OH CDMS; it has been important to receive and incorporate, as appropriate, user feedback we have received to make the system work better for both internal and external users, and will continue to do so. We understand the concern that parties have regarding the data entry requirements; however, these data points are imperative to the functionality of OH CDMS particularly with regards to allowing providers to transfer issues between cases. The information that is entered into the system (as opposed to uploaded via PDF) allows the parties and the Board to better access that information (in whole or in part) for reporting and other purposes. Currently, OH CDMS does not have the ability to pull data out of a PDF, therefore OH CDMS could not provide the necessary reporting and other capabilities to its users if appeals were to be batch uploaded as single PDF files. If in the future this functionality becomes cost-effectively available (and is functionally reliable), we will consider this functionality along with other improvements. Regarding **Federal Register** appeals, in response to feedback from the user community, as of January 2020, users are now able to select a previously-uploaded document in order to save time instead of being required to re-upload the document each time it is needed. We are also considering making similar OH CDMS enhancements for other uploads to facilitate the Board's requisite filing process and will consider all feedback received.

Comment: Commenters were mostly positive and supportive of mandatory electronic filing of PRRB appeals. However, a commenter suggested that the PRRB should not mandate electronic filing stating that it does not allow users the flexibility and security that is required for appeals, and that paper (that is, hard copy) documents were the only acceptable method for filing an appeal for the first 46 years of the Board's history. The commenter added that it would be a mistake to require parties to file all documents electronically during the Covid–19 pandemic, because hospitals are not operating under normal circumstances. The commenter stated that even under normal circumstances, it would be unreasonable to require hospitals and their representative to abandon their internal processes related to filing appeals in paper with only 60 days' notice, as early as this November.

Response: We do not believe it is unreasonable to require hospitals and their representatives to use OH CDMS

for PRRB appeals; many courts have transitioned from paper filing to electronic filing, and the PRRB has received feedback over the years from the provider community requesting the ability to file electronically. We note that the proposed regulation would allow the PRRB to mandate electronic filing with 60 days' notice. The commenter raised concern about having only 60 days' notice of the mandatory use of OH CDMS. However, OH CDMS has been live for close to two years, and there have been various trainings and seminars offered for OH CDMS users, as well as daily Help Desk access for any issues. Notwithstanding, in order to ensure providers have adequate time, we are revising the proposed 60-day notice to require the PRRB to give at least 120 days' notice prior to mandatory use of OH CDMS taking effect. In light of the facts that there are already many registered users of OH CDMS and the majority of filings are now being made using OH CDMS, we believe that this Rule as well as the 120-day advance notice gives Providers and their representatives more than ample time and notice to register for OH CDMS (to the extent they have not already done so), and make any necessary internal changes to processes.

The Covid–19 public health emergency has highlighted the need to have all documents submitted electronically to the PRRB. CMS has maximized telework for the past several months, and while PRRB staff have not been able to access any mail during that time, the PRRB has been able to successfully continue operations largely because it may access the records that have been filed electronically using OH CDMS. Likewise, the need to transition away from paper records, which are vulnerable to risk of fire, flood, loss etc., has become increasingly obvious. Finally, the Federal Government as a whole is moving towards all-electronic records by 2022. *See Memorandum for Heads of Executive Departments and Agencies M–19–21 Transition to Electronic Records* (June 28, 2019), *available at https://www.whitehouse.gov/wp-content/uploads/2019/06/M-19-21.pdf.*

Comment: A commenter stated that provider appeals often require flexibility that is not currently built into OH CDMS, which takes a ''one-size-fits-all'' approach to appeal filings, and does not provide hospitals the opportunity to file an explanation of exigent circumstances. The commenter explained that OH CDMS requires users to make certain certifications to conclusively state that the appeal issues are not pending in any other appeal, but a user can never know with absolute certainty whether another party has mistakenly filed an appeal on the duplicate issue.

Response: With respect to the certifications that are required to be made under Board Rules by the Provider's authorized representative when an appeal is filed, it is reasonable to expect that providers (whether through their authorized internal or external representative(s)) are responsible for knowing any appeals that have been filed, and ensuring that: (1) Duplicate appeals are not made; and (2) if they are part of a provider chain, they establish mandatory group appeals when required by 42 CFR 405.1837(b)(1). Additionally, providers are able to submit any kind of correspondence through OH CDMS once the appeal is established, and could provide an explanation of any exigent circumstances at that time.

Comment: A commenter also stated that there are data security concerns with the OH CDMS user enrollment process, which requires applicants to provide their Social Security Number for a limited credit check. As data breaches can occur, the commenter urged the agency to reconsider requiring personal information for those seeking to file institutional appeals.

Response: The OH CDMS system is integrated within the larger agency-wide CMS Enterprise Portal. The CMS Enterprise Portal relies on the enterprise identity management system (''EIDM'') to authenticate individual users of the system, including where those individuals represent institutional entities. EIDM protects the security of CMS' IT systems and meets CMS, HHS, and other federal government security requirements. In order to keep all CMS IT systems secure, and as required under federal IT security rules, the EIDM process identity proofs individual users before they can access CMS systems. CMS currently conducts this process by using Experian. Experian uses information that it has in its databases to validate the user's identity. Experian's credit information is not shared with CMS, only the positive or negative identity proofing result is shared. In addition, this process is not a credit check but is reflected as a ''soft inquiry'' on the person's credit history.

Comment: Several commenters supported mandatory use of OH CDMS, but suggested that CMS revise the regulatory definition of ''date of receipt'' at 42 CFR 405.1801(a) so that the 5-day presumption does not apply to decision or other documents that the PRRB or another reviewing entity issues electronically to providers. Several comments referred to 42 U.S.C. 1395oo(f)(1) which sets a deadline of 60 days for the Secretary to reverse, affirm, or modify a PRRB decision, therefore the agency does not have the authority to extend this deadline by allowing for a 5-day presumption. One commenter explained that while the 5-day presumption might have been necessary when the PRRB mailed its decisions to providers, now that the PRRB issues all of its decisions electronically, the 5-day presumption is not necessary because all parties to the appeal are notified of the decision instantaneously. The commenter states that similar rules that specifically address email correspondence have been revised to remove the concept of ''presumptive receipt,'' such as Rule 6 of the Federal Rules of Civil Procedure, and the three-day presumption for service of email from 2001 was removed in 2016 because of advances in technology and widespread usage of electronic transmissions. The commenters argued that ''notice'' of the PRRB decision should be based on ''actual'' receipt, which the commenters suggested should be considered to occur upon transmission.

Response: The regulation at 42 CFR 405.1801(a) provides that: ''(iii) The date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity is presumed to be 5 days after the date of issuance of a contractor notice or a reviewing entity document. This presumption, which is otherwise conclusive, may be overcome if it is established by a preponderance of the evidence that such materials were actually received on a later date.''

In the proposed rule, we specifically stated we were not proposing any change in the regulation text defining the ''date of receipt.'' (''We note that we are not proposing to revise the requirement in § 405.1801(a) that the date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity, including the Board, is presumed to be 5 days after the date of issuance. Therefore, regardless of whether the Board issues a decision electronically or by some other means, the 5 day presumption regarding receipt by a party would continue to apply.'' 85 FR 32460, 32865 (May 20, 2020)). We proposed to make limited technical changes to the regulation text to reflect that parties before the Board and the Board itself now file or issue documents in Board cases electronically.

Congress has vested in the Secretary broad rulemaking authority to administer the Medicare program.''

Sebelius v. *Auburn Reg'l Med. Ctr.,* 568 U.S. 145, 156 (2013); *see also* sections 1102(a) and 1871(a)(1) of the Social Security Act. Relying on that authority, the Secretary promulgated the regulation after notice and comment rulemaking. *See* 73 FR 30190, 30193 (May 23, 2008). The 5-day rule continues to be within our statutory authority and is not being revisited in this rule. Even though the rule was originally conceived in the context of paper Board filings and decisions that were sent by regular mail, we continue to believe that the rule is useful and reasonable as it applies equally to providers, the MACs and the reviewing entities themselves and provides needed certainty about when the deadlines run. Among other things, it also ensures continuity on how to calculate the 60 days for a judicial action under 42 CFR 405.1877, regardless of whether the final decision of the Secretary is a decision issued by the PRRB electronically or whether the final decision of the Secretary is a decision issued by the Administrator using regular certified mail. The present regulatory text continues to serve its original purposes to avoid difficult factual disputes regarding the date of receipt through the clarification of the meaning of ''is notified'' and consistent application of a single rule for calculating deadlines, regardless of the means of transmission of the document by the particular reviewing entity. As CMS explained during prior rulemaking, some uniform definition is ''need[ed] to dispel potential confusion'' about when the review period begins to run. 69 FR 35716, 35719 (June 25, 2004). Using a presumption further ''avoid[s] any problem of verifying when a document or other material is actually received,'' (*Id.* at 35719) a burden on parties and courts and reviewing entities. The need for such consistency as a way to avoid disputes has not been made obsolete in the email age.

After consideration of the public comments we received, we are finalizing our FY 2021 proposal to modify regulations in 42 CFR 405 Subpart R to allow the PRRB to mandate electronic filing of appeals. We are modifying our proposal, however, to give 120 days' notice prior to mandatory use of OH CDMS taking effect, rather than the 60 days' notice that was proposed.

C. Revisions of Medicare Bad Debt Policy

1. Background

Under the Medicare program, beneficiaries may be responsible for payments of premiums, copayments, deductibles (including blood deductibles), and coinsurance amounts that are related to covered services (42 CFR 409.80 through 409.89). The Medicare program recognizes that a beneficiary's failure to pay a deductible or coinsurance amount could lead to non-Medicare patients bearing the related costs of covered Medicare services, a result that is barred by the statutory prohibition on the cross-subsidization of the Medicare program by non-Medicare patients, as set out at section 1861(v)(1)(A)(i) of the Act (*see also* 42 CFR 413.89(d)).

Medicare pays beneficiaries' unpaid deductible and coinsurance amounts for covered services if such services are reimbursed by the program on the basis of reasonable cost or paid under a cost-based prospective payment system. Thus, the following amounts are not included as allowable bad debts under Medicare:

- Unpaid Medicare deductible and coinsurance amounts associated with furnishing non-covered services and services furnished to non-Medicare patients.
- Unpaid Medicare premiums and Medicare copayments [510] associated with any covered service.
- Unpaid Medicare deductible and coinsurance amounts associated with any covered services paid by the program under a fee schedule or under a reasonable charge-based methodology including Program fee schedule payments made to physicians (and payments to providers on behalf of provider-based physicians) for professional services and fee schedule payments made to other practitioners.
- Unpaid Medicare deductible and coinsurance amounts associated with covered services paid for under a contractual capitated rate-based plan, such as but not limited to, a Medicare Advantage plan.
- Unpaid Medicare deductible and coinsurance amounts written off to charity care.
- Unpaid Medicare deductible and coinsurance amounts written off to a contractual allowance account.

In accordance with section 1861(v)(1) of the Act and our regulations at § 413.89, Medicare pays some of the uncollectible deductible and coinsurance amounts to certain providers, suppliers and other entities (hereinafter collectively referred to as ''providers'') eligible to receive reimbursement for bad debt of Medicare beneficiaries. Sections 1815(a) and 1833(e) of the Act state that no Medicare payments will be made to a provider unless it has furnished information requested by the Secretary to determine payment amounts due under the Medicare program. To determine if bad debt amounts are allowable, providers must meet the requirements at § 413.89, and Chapter 3, Bad Debts, Charity, and Courtesy Allowances, of the Provider Reimbursement Manual (PRM) (CMS Pub. 15–1) (hereinafter referred to as PRM), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929,* which provides further explanation and instruction regarding the requirements for Medicare bad debt reimbursement.

The reimbursement of Medicare bad debt was not originally statutorily mandated; rather, it was first promulgated by CMS [511] in 1966 [512] shortly after the Medicare Program's inception and was thereafter set forth in the regulations.[513] Congress later statutorily created reimbursement limits on allowable Medicare bad debt under section 1861(v)(1)(T), (V) and (W) of the Act. The regulations at § 413.89(b)(1) define ''bad debts'' as amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. Accounts receivable and notes receivable are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future. Similar language is set forth in the PRM § 302.1. To be an allowable Medicare bad debt, the debt must meet all of the following criteria (see § 413.89(e) and PRM § 308):

- The debt must be related to covered services and derived from deductible and coinsurance amounts.
- The provider must be able to establish that reasonable collection efforts were made.

[510] While copayments and coinsurance amounts are both amounts of Medicare beneficiary cost sharing, a copayment is usually a fixed amount a beneficiary may be required to pay as their share of cost for a medical service or supply (for example, a doctor's visit, hospital outpatient visit, or prescription drug). Unpaid copayments are excluded from bad debt reimbursement. Conversely, a coinsurance amount is usually an amount a beneficiary may be required to pay as a percentage share of cost with the Medicare plan for services after the payment of any applicable deductible.

[511] To implement the Medicare statute, the Social Security Administration (SSA) was reorganized and the Bureau of Health Insurance (BHI) was established on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed CMS. CMS Milestones 1937–2015 (July 2015).

[512] November 22, 1966 (31 FR 14813).

[513] The current Medicare bad debt regulations were originally proposed and finalized in 1966 and codified at § 405.420.

• The debt was actually uncollectible when claimed as worthless.

• Sound business judgment established that there was no likelihood of recovery at any time in the future.

In 1987, Congress enacted legislation that implemented a moratorium prohibiting the Secretary and contractors from making changes to Medicare bad debt reimbursement policies that were in effect on August 1, 1987 for hospitals. This is typically referred to as the ''Bad Debt Moratorium.'' (*See* section 4008(c) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203)). In section 3201 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), the Bad Debt Moratorium was repealed by Congress, effective for cost reporting periods beginning on or after October 1, 2012.

Because the Bad Debt Moratorium is no longer in existence, we believe it is appropriate to clarify certain Medicare bad debt policies that have been the subject of litigation, and generated interest and questions from stakeholders over the past several years. Hence, in the FY 2021 IPPS proposed rule, we proposed to clarify, update and codify certain longstanding Medicare bad debt principles into the regulations by revising § 413.89, ''Bad debts, charity, and courtesy allowances.'' We also solicited comments from stakeholders that we could consider to finalize a process to accept alternate documentation to the Medicaid remittance advice (RA) to determine a state's cost sharing liability for dual eligible beneficiaries in instances where a state has a Medicare cost sharing liability but does not issue the provider a Medicaid RA due to the state's non-recognition of a Medicare provider for Medicare crossover cost sharing determinations. Additionally, we proposed to recognize the new Accounting Standards Update—Topic 606 for revenue recognition and classification of Medicare bad debts. We also proposed technical corrections to the incorrect cross references in 42 CFR 412.622 and 417.536 to refer to the Medicare bad debt reimbursement regulation at § 413.89.

We proposed that the clarification and codification of our longstanding Medicare bad debt policies, where indicated herein, be effective for cost reporting periods beginning before, on, and after the effective date of this rule, because of the important public interest it would serve to do so as set forth in section 1871(e)(1)(A)(ii) of the Act. Our specific proposals for revising our regulations, the public comments received, and implementation decisions are discussed in this section of this rule.

2. Revisions to Regulations

a. Reasonable Collection Effort, Non-Indigent Beneficiaries

Providers are permitted to collect unpaid Medicare cost sharing amounts from beneficiaries, unless beneficiaries have been determined to be categorically or medically needy by State Medicaid Agencies to receive medical assistance from Medicaid, or determined to be indigent by the provider for Medicare bad debt purposes. If a beneficiary's Medicare cost sharing remains unpaid, in order to claim reimbursement from Medicare for the bad debt, providers must demonstrate that they have first made a reasonable effort to collect the beneficiary's unpaid deductible and/or coinsurance amounts. (See § 413.89(e)(2) and the PRM § 310.) This reasonable effort to collect the unpaid deductible and coinsurance amounts is, in part, based on the provider applying sound business judgment and has been a longstanding Medicare bad debt policy requirement articulated in the PRM since 1968. The PRM § 310 describes a ''reasonable collection effort'' and sets forth how providers must effectuate the reasonable collection effort, as a precondition to reimbursement of a provider's bad debt. We note that the provider's required collection efforts set forth in PRM § 310 apply only to non-indigent beneficiaries; the provider's required collection efforts are different for beneficiaries who have been determined by the provider to be indigent, including medically indigent, or beneficiaries enrolled in Medicaid. In the proposed rule, we proposed to clarify and codify the distinction between non-indigent beneficiaries and indigent beneficiaries for Medicare bad debt purposes.

Specifically, we proposed to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i) to define, for Medicare bad debt purposes, a non-indigent beneficiary as a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, and has not been determined to be indigent by the provider for Medicare bad debt purposes.

These proposals would be effective for cost reporting periods beginning before, on, and after the effective date of this rule because the difference in collection efforts required by a provider for indigent and non-indigent beneficiaries has existed since the promulgation of Medicare bad debt policy and the definition of a non-indigent beneficiary codifies the existing meaning of the term.

Comment: Some commenters were supportive of the proposal to codify the definition of a non-indigent beneficiary because it would provide clarity to the Medicare bad debt policies. Other commenters suggested that the codification of the definition for this beneficiary category did not serve an important interest and should not be applied retroactively.

Response: We appreciate the commenters' suggestions and perspectives. Because the longstanding Medicare bad debt rules requiring a provider's reasonable collection effort are different for beneficiaries who are either non-indigent, beneficiaries who have been determined by the provider to be indigent, including medically indigent, or beneficiaries enrolled in Medicaid, we believe that as we clarify and codify these longstanding bad debt policies, it is important to set forth the definition of each beneficiary category so that it is clear which bad debt policies applied, and continue to apply, to each. We believe that the retroactive codification of the definition of a non-indigent beneficiary serves to promote a public interest to provide clarity because the definition has existed inherently in the longstanding bad debt collection effort policies that applied, and continue to apply, to a non-indigent beneficiary. Our longstanding Medicare bad debt rules in the PRM requiring a provider's reasonable collection effort are different for beneficiaries who are non-indigent and beneficiaries who have been determined by the provider to be indigent (including medically indigent) or beneficiaries enrolled in Medicaid. Providers must follow reasonable collection effort procedures set forth in PRM § 310 for non-indigent beneficiaries, procedures set forth in PRM § 312 for beneficiaries determined by the provider to be indigent, and procedures described in PRM § 322 for beneficiaries enrolled in Medicaid. Therefore, we believe that as we clarify and codify these longstanding bad debt policies, it is important to set forth the definition of each of these three beneficiary categories so that it is clear which bad debt collection effort policy applied, and continue to apply, to each. We believe that providers will not be burdened or harmed by the application and formalization of a label and definition for this beneficiary category.

Our longstanding bad debt policies have existed in Medicare guidance, including the PRM, for several decades and providers and beneficiaries are

familiar with and rely upon them. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date does not affect prior transactions or impose additional duties or adverse consequences upon providers or beneficiaries, nor does it diminish rights of providers or beneficiaries. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date also serves an important public interest to assist providers and beneficiaries by avoiding confusion as to which longstanding policy should be applied for which cost reporting period, as might arise if the effective date was instead proposed for cost reporting periods beginning on or after the effective date of this rule. Failing to adopt the clarification and codification of longstanding Medicare bad debt policies with a retroactive effective date might lead some providers to believe that those policies did not apply to earlier cost reporting periods, and thus might cause those providers to resubmit previously submitted cost reports. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date serves the important public interest of promoting fairness and economy to providers by saving them the time and resources required for such resubmissions, and by saving government resources and funds from the taxpayer-funded Medicare Trust Fund that would be expended in review of cost report resubmissions. These considerations apply equally to all aspects of this final rule that we are finalizing with a retroactive effective date.

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i) to define, for Medicare bad debt purposes, a non-indigent beneficiary as a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, and has not been determined to be indigent by the provider for Medicare bad debt purposes. This provision will be effective for cost reporting periods beginning before, on, and after the effective date of this rule.

(1) Issuance of a Bill for Non-Indigent Beneficiaries, PRM Section 310

Under Medicare bad debt policy, a provider is required to demonstrate that it has made a reasonable effort to collect beneficiaries' unpaid deductibles and coinsurance amounts. PRM § 310 sets forth that to be considered a reasonable collection effort, a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients. It must involve the issuance of a bill on or shortly after discharge or death of the beneficiary to the party responsible for the patient's personal financial obligations. It also includes other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort. The provider's collection effort may include using or threatening to use court action to obtain payment.

Generally, providers will have financial incentives to issue bills to patients as soon as possible to collect the outstanding debt and remove it from their financial records, or present beneficiaries' unpaid deductible and coinsurance amounts to Medicare after a reasonable collection effort period for reimbursement of the Medicare reimbursable amount.

Over the past several years, we have received feedback from stakeholders indicating that ''shortly after'' in PRM § 310 is too vague, as well as inquiries as to what timeframe ''shortly after'' means for providers to comply with the reasonable collection effort. Stakeholders have suggested that ''shortly after'' could be anywhere from 30 days to a year following the discharge or death of the beneficiary. The Merriam Webster definition of ''short(ly)'' [514] is ''not extended in time,'' ''brief,'' ''expeditious,'' or ''quick.'' Although the timeframe ''shortly after'' was drafted in the PRM § 310 decades ago with an eye toward affording flexibility to providers, inquiries from stakeholders and variances in the application of ''shortly after'' over the years have led us to believe that a more definitive timeframe should be considered while still maintaining the greatest flexibility for providers.

We believe that a timeframe of 30 or 60 days would be too short because it may not allow providers with varying billing practices the ability to issue the bill within that timeframe. A timeframe of 90 or 120 days would afford greater flexibility, as we have found this to be in the upper parameters of most providers' billing practices for the issuances of bills to patients.

In addition to the queries over the definition of ''shortly after,'' stakeholders have questioned whether the benchmark event for the issuance of the bill should be the ''discharge or death of the beneficiary,'' or some other event. Generally, Medicare fee for service claims must be filed with the appropriate Medicare claims processing contractor no later than 12 months, or 1 calendar year, after the date the services were furnished (42 CFR 424.44). For institutional providers that have a span of dates of services (that is, from X date through Y date), the ''through'' date (that is, the last day of service) is used as the date of service for the 12 month (or 1 calendar year) timeframe for a provider to timely submit a bill (CMS Pub. 100–04, section 70.4). Following the processing of the claim, the provider receives a Medicare remittance advice evidencing the claim processing. Because providers have 12 months from the date of service to timely submit a bill to Medicare, we believe that requiring a provider to issue a bill for the beneficiary's unpaid cost sharing following the ''discharge or death of the beneficiary'' is a much shorter timeframe and does not afford flexibility to the provider when the provider has a much longer timeframe of 12 months from the date a service was provided to bill Medicare in accordance with the billing requirements. We note that providers usually issue a bill to a beneficiary, or the party who is financially responsible for the beneficiary's personal financial obligations, within 120 days of death or discharge. We believe that a more flexible option could be to require the provider to issue a bill for Medicare cost sharing no later than 120 days following the provider's receipt of the Medicare remittance advice for the processed claim, because this is similar to providers' usual billing timeframes, or some other event as discussed herein.

We have received suggestions from stakeholders that the benchmark event for the provider to issue a bill to the beneficiary for Medicare cost sharing should be after the provider's receipt of payment from the beneficiary's secondary payer,[515] if any. In this instance, a beneficiary may have other insurance, secondary to Medicare, which may also have a coverage liability to pay for the service provided to the beneficiary. Secondary insurance may pay some or all of the costs left after the primary insurer, Medicare, has paid (for example, deductibles and/or coinsurance amounts). In this regard,

[514] *https://www.merriam-webster.com/dictionary/short.*

[515] This secondary payer is other than Medicaid for a dual eligible beneficiary.

the provider must bill Medicare and the secondary payer in order to determine the beneficiary's accurate and outstanding Medicare cost sharing liability. Because there is no minimum date by which a provider must issue a bill to the party responsible for the beneficiary's cost sharing, and providers can claim Medicare bad debt in the cost reporting period in which the debt was deemed worthless, there is no disadvantage to the provider for us to adopt one or all of the aforementioned benchmark scenarios upon which a provider must issue a bill.

Longstanding Medicare bad debt policy also requires that a provider's reasonable collection effort include other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than token, collection effort.'' Additionally, a provider must furnish documentation to its contractor that includes the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the beneficiary's account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and the beneficiary's file with copies of the bill(s) and follow-up notices.

Therefore, we proposed to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A) to specify the reasonable collection effort requirement for a non-indigent beneficiary must be similar to the effort the provider, and/or the collection agency acting on the provider's behalf, puts forth to collect comparable amounts from non-Medicare patients. It must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after: (1) The date of the Medicare remittance advice; or (2) the date of the remittance advice from the beneficiary's secondary payer, if any; whichever is latest. A provider's reasonable collection effort also includes other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than token, collection effort. Additionally, a provider must maintain and, upon request, furnish documentation to its contractor that includes the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the beneficiary's account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and the beneficiary's file with copies of the bill(s) and follow-up notices.

We proposed that these revisions, except for § 413.89(e)(2)(i)(A)(*2*) and (*3*), would be effective for cost reporting periods beginning before, on and after the effective date of this rule. The provisions proposed in § 413.89(e)(2)(i)(A)(*3*), regarding the requirement to issue a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations based on the remittance advice date from Medicare or the beneficiary's secondary payer, if any, would be effective for cost reporting periods beginning on or after the effective date of this rule.

We also proposed that § 413.89(e)(2)(i)(A)(*2*), regarding the prior longstanding Medicare bad debt policy requiring the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary, would be effective for cost reporting periods beginning before the effective date of this final rule.

Comment: We received many comments in support of our attempt to clarify what constitutes a reasonable collection effort for non-indigent beneficiaries and set forth the timeframe within which a provider must issue a bill to commence its reasonable collection effort. Many commenters agreed that the longstanding policy benchmark event, ''shortly after death or discharge of the beneficiary'' as set forth in the PRM, § 310 was vague and subject to interpretation. Some commenters requested that the proposed timeframe within which to issue a bill to the beneficiary in proposed § 413.89(e)(2)(i)(A)(*3*) also include a third circumstance of the date of the notification that the beneficiary's secondary payer does not cover the service furnished to the beneficiary.

Response: We appreciate commenters' support of our proposals to clarify the timeframe within which a provider must issue a bill to a non-indigent beneficiary to commence its reasonable collection effort. We agree with providers that there may be instances when a provider's reasonable collection effort should commence following a notification of no coverage from a beneficiary's secondary payer. To keep this event objective, consistent and auditable we agree that the third benchmark timeframe, within which a provider must issue a bill to a non-indigent beneficiary to commence its reasonable collection effort, should be the date on the notification of no coverage from the beneficiary's secondary payer, as opposed to the more subjective and immeasurable date when the provider receives the notification of no coverage from the secondary payer.

Comment: A few commenters requested that we further define what constitutes a provider's personal contacts with beneficiaries to collect the unpaid deductibles and coinsurance amounts, and whether personal contacts can include communication methods such as email and text message.

Response: We appreciate commenters' inquiries and believe that a provider's reasonable collection effort as set forth in the PRM includes a provider's actions ''such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than token, collection effort.'' We note that the definition of a ''personal contact'' means an encounter where two or more people are in visual or physical proximity to each other or a face-to-face encounter.[516] We believe that a provider's reasonable collection effort that can include subsequent billings, collection letters and telephone calls or personal contacts with the beneficiary or responsible party, as long as the collection effort constitutes a genuine, rather than a token, collection effort, can also include other actions such as sending electronic communications (for example, emails and text messages) as long as they also constitute a genuine, rather than a token, collection effort, and are auditable and verifiable.

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(1) through (4) to specify the reasonable collection effort requirement for a non-indigent beneficiary must be similar to the effort the provider, and/or the collection agency acting on the provider's behalf, puts forth to collect comparable amounts from non-Medicare patients. For cost reporting periods beginning before October 1, 2020, a provider's collection effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary. For cost

[516] *https://www.lawinsider.com/dictionary/personal-contact#:~:text=Personal%20contact%20means%20an%20encounter,include%20these%20types%20of%20contacts.*

reporting periods beginning on or after October 1, 2020, a provider's collection effort must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following: (1) The date of the Medicare remittance advice that is produced from processing the claim for services furnished to the beneficiary that generates the beneficiary's cost sharing amounts; (2) the date of the remittance advice from the beneficiary's secondary payer, if any; and (3) the date of the notification that the beneficiary's secondary payer does not cover the service(s) furnished to the beneficiary. A provider's reasonable collection effort must also include other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party.

(2) 120-Day Collection Effort and Reporting Period for Writing Off Bad Debts

Under Medicare bad debt policy, PRM § 310.2 sets forth a ''presumption of noncollectibility,'' which provides that if after reasonable and customary attempts to collect a bill, the debt remains unpaid more than 120 days from the date the first bill is mailed to the beneficiary, the debt may be deemed uncollectible.

This means that a provider must make reasonable and customary attempts to collect a bill for at least 120 days from (and including) the date the first bill is mailed to the beneficiary (or the party responsible for the beneficiary's personal financial obligations), including when a provider uses a collection agency to collect a bill. If the debt remains unpaid on the 121st day from the date the first bill is mailed to the beneficiary, the provider can cease collection efforts and presume that the account is non-collectible, and designate the unpaid deductible and coinsurance amounts as an uncollectible bad debt.

Over the past several years, questions have arisen from stakeholders with regard to the effect on the collection effort when a provider receives partial payments during the 120-day collection effort time period. We have always intended that when a partial payment is received within the required 120-day collection effort period, the collection effort is not completed and the 120-day time period restarts on the day the partial payment is received. The language in the PRM § 310.2 supports this interpretation, as it sets forth ''if, after 120 days, a payment is not received, the unpaid amount can be written off.'' We have implemented a policy that if, within the 120 days, a partial payment is received, the remaining uncollected amount cannot be written off to Medicare bad debt because the collection effort is active and ongoing by way of the response from the beneficiary submitting a payment. The partial payment received evidences the beneficiary's willingness to pay the debt, at least in part, and the provider must further engage with the beneficiary and follow up, by way of continuing the collection effort and sending additional collection letters or bills to the beneficiary for another 120-day collection effort time period. It is reasonable to place a date of finality on the collection effort time period; hence, the 120-day minimum collection time period. However, when partial payments are received within the 120-day time period, it is reasonable to presume the remaining unpaid amount is collectible and expect the provider to continue the collection effort instead of presuming it to be non-collectible and requesting Medicare to reimburse the provider for what the beneficiary is actively engaging to pay. This constitutes a reasonable collection effort as required by § 413.89(e)(2).

Requiring the 120-day collection effort timeframe to start anew when a partial payment is received during the 120 days is not burdensome to the provider and requires little additional resources from the provider because the account is still open on the provider's accounting books, and has not yet been written off as a bad debt. Additionally, because ''uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless,'' (PRM § 314), the provider can claim the unpaid amounts as a Medicare bad debt after the additional 120-day collection effort time period, provided that no additional payment is received that would require an extension of the 120-day collection effort time period again.

We proposed to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(*5*)(*ii*) to specify that when the provider receives a partial payment within the minimum 120-day required collection effort period, the provider must continue the collection effort and the day the partial payment is received is day one of the new collection period. For each subsequent partial payment received during a 120-day collection effort period, the provider must continue the collection effort and the day the subsequent partial payment is received is day one of the new collection period. The provider is permitted to end the collection effort at the end of a 120-day collection effort period when no payments have been received during those consecutive 120 days. These revisions would be effective for cost reporting periods beginning before, on and after the effective date of this final rule because we proposed to clarify and codify our longstanding policy pertaining to the required 120-day collection effort.

We also proposed to clarify and codify into the regulations our longstanding policy regarding the reporting periods and recovery of bad debts, which specifies required procedures for when a provider recovers (that is, receives a payment in the current year) an amount that was previously claimed and paid as a Medicare bad debt, in a prior cost reporting period. In some cases an amount written off as a bad debt and reimbursed by the program in a prior cost reporting period may be recovered in a subsequent accounting period; in such situations, the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered. However, the amount of such reduction in the period of recovery must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period. Because this is has been our longstanding policy as set forth in the PRM and the regulations for several decades, we proposed to clarify this policy in the regulations to also apply to cost reporting periods beginning before, on and after the effective date of this final rule. We also proposed to amend § 413.89(f) by adding language to specify that, effective for cost reporting periods beginning before, on and after October 1, 2020, the deductible and coinsurance amounts uncollected from beneficiaries are to be written off and recognized as allowable bad debts in the cost reporting period in which the accounts are deemed to be worthless. Any payment on the account made by the beneficiary, or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report.

Comment: Some commenters were supportive of the proposal to codify the longstanding Medicare bad debt 120-day collection effort required by providers from non-indigent beneficiaries. However, many commenters were not supportive of our proposal to codify our longstanding collection effort policy requiring the provider engage in a continuous 120-day collection effort with no payment received, as they

believed doing so would unnecessarily require them to keep their accounts receivable open for longer periods of time. Commenters were not supportive of a retroactive effective date for the codification of this provision, as they believed providers would be confused by the applicability of the policy for various cost reporting periods and suffer harm.

Response: We respectfully disagree with commenters. Longstanding Medicare bad debt policy regarding the presumption of noncollectibility, as set forth in the PRM § 310.2 supports a continuous 120-day period without a payment as part of a reasonable collection effort. Section 310.2 states that ''if, after 120 days, a payment is not received, the unpaid amount can be written off.'' We therefore have concluded that if, within the 120 days, a partial payment is received, the remaining uncollected amount cannot be written off to Medicare bad debt because the collection effort is active and ongoing by way of the response from the beneficiary submitting a payment. Our longstanding position, asserted in court cases and legal documents over the years, is that if the provider continues to receive money, then the account is not a worthless account without value. The account has some recovery value when payments continue to be received and therefore, it is appropriate for the provider to keep the account open for an additional collection period to attempt further collection efforts before presenting the unpaid amounts as a Medicare bad debt which is funded by the Medicare Trust Fund and comprised of taxpayer money. This longstanding bad debt policy has existed in Medicare guidance, including the PRM, for decades, and providers and beneficiaries are familiar with and rely upon it. The clarification and codification of this longstanding Medicare bad debt policy into the regulations with a retroactive effective date does not affect prior transactions or impose additional duties or adverse consequences upon providers or beneficiaries, nor does it diminish rights of providers or beneficiaries. The clarification and codification of this longstanding Medicare bad debt policy into the regulations with a retroactive effective date also serves an important public interest to assist providers and beneficiaries by avoiding confusion as to which longstanding policy should be applied for which cost reporting period, as might arise if the effective date was instead proposed for cost reporting periods beginning on or after the effective date of this rule. Failing to adopt the clarification and codification of longstanding Medicare bad debt policies with a retroactive effective date might lead some providers to believe that those policies did not apply to earlier cost reporting periods, and thus might cause confusion among some providers or cause others to resubmit previously submitted cost reports. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date serves the important public interest of promoting fairness and economy to providers by saving them the time and resources required for such resubmissions, and by saving government resources and funds from the taxpayer-funded Medicare Trust Fund that would be expended in review of cost report resubmissions. These considerations apply equally to all aspects of this final rule that we are finalizing with a retroactive effective date.

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(5)(*i*) to specify that a provider's reasonable collection effort requirement for a non-indigent beneficiary must also last at least 120 days after § 413.89(e)(2)(i)(A)(2) or (3) is met before being written off as uncollectible under paragraph § 413.89(e)(3). We are finalizing our proposal to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(5)(*ii*), effective for cost reporting periods beginning before, on, and after the effective date of this rule, to specify that a provider's reasonable collection effort requirement for a non-indigent beneficiary must also start a new 120-day collection period each time a payment is received within a 120-day collection period.

(3) Similar Collection Effort Required, Including Collection Agency Use, PRM Section 310

Under Medicare bad debt policy, Medicare regulations at § 413.89(e)(2) require that providers engage in reasonable collection efforts. Our manual guidance currently states that, ''[t]o be considered a reasonable collection effort, a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.'' PRM § 310. As such, a provider's dissimilar debt collection practices for Medicare and non-Medicare patient accounts do not constitute a provider's ''reasonable collection effort'' to claim reimbursement from Medicare for a bad debt, whether the collection effort from the provider is an in-house collection effort or if the provider elects to refer bad debt accounts to a collection agency for an outside collection effort. This policy has been the subject of dispute by stakeholders in the past and we believe that a clarification of the policy is necessary with incorporation of the PRM guidance into the regulations.

If a provider elects to refer its non-Medicare accounts to a collection agency, the provider must similarly refer its Medicare accounts of ''like amount.'' The PRM § 310.A states that where a collection agency is used, Medicare expects the provider to refer all uncollected patient charges of like amount to the agency without regard to class of patient. The ''like amount'' requirement may include uncollected charges above a specified minimum amount. Therefore, if a provider refers to a collection agency its uncollected non-Medicare patient charges which in amount are comparable to the individual Medicare deductible and coinsurance amounts due the provider from its Medicare patient, Medicare requires the provider to also refer its uncollected Medicare deductible and coinsurance amounts to the collection agency.

When the provider uses a collection agency to perform a reasonable collection effort on its behalf, the provider must ensure that the collection agency's collection effort is similar to the effort the collection agency puts forth to collect comparable amounts from non-Medicare patients. This means that for similar, comparable amounts of the collection accounts, the collection agency must use similar collection practices for both accounts.

The collection agency's collection effort can include subsequent billings, collection letters, and telephone calls or personal contacts with the party who is financially responsible for the beneficiary's personal financial obligation which constitute a genuine, rather than a token, collection effort. The collection agency's collection effort may also include using or threatening to use court action to obtain payment. Where the collection agency does not follow the reasonable collection effort requirement, Medicare does not recognize the fees as an allowable administrative cost. Collection accounts that remain at a collection agency, for whatever reason, including accounts that are monitored passively by the collection agency, cannot be claimed by the provider as a Medicare bad debt. This is because during the period the unpaid account remains at the

collection agency, the provider cannot meet the fourth regulatory requirement in § 413.89(e)(4) that ''sound business judgment established that there was no likelihood of recovery at any time in the future.'' While an account remains at a collection agency, there is always a likelihood of at least some recovery on the account. The purpose of having an account at a collection agency is to collect on the account, even if the account is in a passive collection status. Hence, the very act of having an account at a collection agency is deemed to be a collection effort undertaken by the provider. As such, the provider cannot establish that there is ''no likelihood of recovery at any time in the future'' for the account and the provider is unable to claim the account as an allowable Medicare bad debt.

The fee charged by the collection agency is its charge for providing the collection service and is not considered a Medicare bad debt. Where a provider uses the services of a collection agency and the collection agency performs a reasonable collection effort, Medicare recognizes the fees the collection agency charges the provider as an allowable administrative cost. When a collection agency obtains payment of an account receivable, the gross amount collected reduces the patient's account receivable by the same amount and must be credited to the patient's account. The collection fee deducted by the agency is charged to administrative costs.

Example 1—Collection Agency Charges Percent Fee

The provider sends a beneficiary's account of $400 to the collection agency and the collection agency's fee for its service is 30 percent of the collected amount. If the collection agency collects $220 from the beneficiary, the collection agency keeps $66 (30 percent of $220) as its fee for the collection services and remits $154 ($220 less $66) to the provider. The provider records the full amount collected by the collection agency ($220) in the beneficiary's account receivable and records the collection fee ($66) in administrative costs. Once the collection agency completes the required collection efforts on this account, returns the account back to the provider and the provider deems the account worthless, the provider can claim on its cost report the amount of $180 ($400 less $220) as a Medicare bad debt (subject to further statutorily mandated reductions as set forth in § 413.89(h)). The provider cannot claim the $66 collection agency fee as a Medicare bad debt.

Example 2—Collection Agency Charges Flat Fee

The provider sends a beneficiary's account of $400 to the collection agency and the collection agency's flat fee is $100 per account for its services. If the collection agency collects $250 from the beneficiary, the collection agency keeps $100 as its fee for the collection services and remits $150 ($250 less $100) to the provider. The provider records the full amount collected by the collection agency ($250) in the beneficiary's account receivable and records the collection fee ($100) in administrative costs. Once the collection agency completes the required collection effort on this account, returns the account back to the provider and the provider deems the account worthless, the provider can claim on its cost report the amount of $150 ($400 less $250) as a Medicare bad debt (subject to further statutory mandated reductions as set forth in § 413.89(h)). The provider cannot claim the $100 collection agency fee as a Medicare bad debt.

Therefore, we proposed to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A) to specify that a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients. A provider's dissimilar debt collection practices for Medicare and non-Medicare patient accounts do not constitute a reasonable collection effort to claim reimbursement from Medicare for a bad debt, whether the collection effort from the provider is an in-house collection effort or if the provider elects to refer bad debt accounts to a collection agency for an outside collection effort. A provider may use a collection agency to perform a reasonable collection effort on its behalf. The provider must ensure that the collection agency's collection effort is similar to the effort the collection agency puts forth to collect comparable amounts from non-Medicare patients. The collection agency's collection effort can include subsequent billings, collection letters, and telephone calls or personal contacts with the responsible party which constitute a genuine, rather than a token, collection effort. The collection agency's collection effort may include using or threatening to use court action to obtain payment. The fee charged by the collection agency is its charge for providing the collection service and is not considered a Medicare bad debt. Where a provider uses the services of a collection agency and the collection agency performs a reasonable collection effort, Medicare recognizes the fees the collection agency charges the provider as an allowable administrative cost. Where the collection agency does not follow the reasonable collection effort requirement, Medicare does not recognize the fees as an allowable administrative cost. Collection accounts that remain at a collection agency, for whatever reason, including accounts that are monitored passively by the collection agency, cannot be claimed by the provider as a Medicare bad debt. When a collection agency obtains payment of an account receivable, the gross amount collected reduces the patient's account receivable by the same amount and must be credited to the patient's account. The collection fee deducted by the agency is charged to administrative costs.

These revisions would be effective for cost reporting periods beginning before, on and after the effective date of this final rule because we are clarifying and codifying our longstanding policy.

Comment: Some commenters suggested that CMS abandon the proposal to codify the requirement that accounts remaining at a collection agency cannot be considered for Medicare bad debt because accounts at a collection agency have little to no value and providers simply place them with collection agencies for the small possibility of a collection. Some commenters cited federal court decisions and asserted that they foreclosed our adoption of similar collection effort policies. Other commenters suggested that if a payment were to be made on an account while at a collection agency, providers could reconcile the amount paid and record it as a recovery on the provider's subsequently submitted cost report.

Response: We appreciate commenters' suggestions but respectfully disagree. The current Medicare bad debt regulation requires that to be allowable, a bad debt must be ''actually uncollectible when claimed as worthless,'' and also that ''sound business judgment established that there was no likelihood of recovery at any time in the future.'' § 413.89(e)(3) and (4). It has been our longstanding policy that an account that remains at a collection agency has satisfied neither of these regulatory conditions, remains in a collection effort status, and thus cannot be claimed as a Medicare bad debt. An account that remains at a collection agency still holds some value for the chance of a recovery and there is a possibility, a likelihood, of recovery while the account remains there. We have also reviewed the federal court decisions cited in some comments and

do not agree that they prevent us from adopting the rules regarding similar collection efforts that we are finalizing.

Comment: Some commenters suggested that further definitions be set forth for what constitutes a genuine, and not a token collection effort.

Response: A genuine, rather than a token, collection effort is based on the reasonableness of a provider's effort to collect the unpaid Medicare deductible and coinsurance amounts from the beneficiary or responsible party. It entails a serious and concerted effort by the provider to collect the unpaid debt. The provider's genuine, rather than token, collection effort has been addressed in PRM § 310 under the concept of ''reasonable collection effort'' as ''also include[ing] other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort.'' As we have asserted in the past in policy statements and proceedings, a genuine collection effort requires the provider to engage in prompt and continuous collection efforts, over at least 120 days, advising the beneficiary of the amounts to be collected, engaging in subsequent follow up and billing, and may include the provider engaging a collection agency.

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A) to specify that a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.

(4) Documentation Required—Reasonable Collection Effort for Non-Indigent Beneficiaries

Medicare's longstanding bad debt policy requires that as part of a provider's reasonable collection effort for beneficiaries, including non-indigent beneficiaries, the provider must maintain and, upon request, furnish to the Medicare contractor documentation of the provider's collection effort, whether the provider performs the collection effort in house or whether the provider uses a collection agency to perform the required collection effort on the provider's behalf. PRM § 310.B. The documentation of the collection effort must include: The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; and the patient account history documents which show the dates of various collection actions such as the issuance of bills, follow-up collection letters, reports of telephone calls and personal contact, etc. Unpaid deductible and coinsurance amounts without collection effort documentation are not allowable bad debts.

Therefore, we proposed to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(*6*) to specify the requirements a provider must follow in order to document the provider's reasonable collection effort for non-indigent beneficiaries.

Because these are clarifications of codifications of longstanding Medicare bad debt policy, these policies would be effective for cost reporting periods beginning before, on and after the effective date of the final rule.

Comment: Some commenters disagreed with the proposal that documentation requirements for a provider's collection effort be codified. Some commenters suggested that documentation practices can vary among providers and are subject to interpretation by contractors. Commenters instead suggested that the documentation requirements be set forth in subregulatory guidance.

Response: We appreciate commenters' concerns but respectfully disagree. We note that regulatory guidance exists at 42 CFR 413.20 and 413.24 regarding providers' recordkeeping and documentation requirements to substantiate payment. We also note other regulations set forth specific documentation requirements, for example, 42 CFR 413.75 for direct GME payments. We believe that our rules governing documentation requirements for a provider's reasonable collection effort should be similarly appropriately codified in regulations text. Such codification will provide clarity and should therefore minimize the possibility of varying interpretations that have caused some commenters' concerns. We also, however, believe the requirements are general enough to afford needed flexibility to providers.

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(6) to specify the requirements a provider must follow in order to document the provider's reasonable collection effort for non-indigent beneficiaries. Specifically, providers must maintain and, upon request, furnish verifiable documentation to its contractor that includes all of the following: (*i*) The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients, (*ii*) The patient account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and (*iii*) The beneficiary's file with copies of the bill(s) and follow-up notices. We will evaluate the burden estimates for the recordkeeping requirements in all applicable cost reports, such as OMB Control No. 0938–0050 (Hospitals and Health Care Complex Cost Report), and if these recordkeeping activities have not been accounted for we will revise the ICR(s) via a Paperwork Reduction Act notice.

b. Reasonable Collection Effort, Beneficiaries Determined Indigent by Provider Using Required Criteria

Under PRM § 312, a provider may determine a beneficiary to be indigent for purposes of claiming a beneficiary's unpaid deductible and/or coinsurance amounts as a Medicare bad debt. A provider can determine a beneficiary's indigence in one of two ways: (1) When the beneficiary is eligible for Medicaid as either a categorically or medically needy individual (that is, a dual eligible Medicare beneficiary); or (2) the provider determines a non-dual eligible Medicare beneficiary, to be indigent by applying the provider's customary methods for determining a patient to be indigent under the evaluation criteria in PRM § 312. A. through D. Once indigence is determined by the provider, and the provider concludes that there has been no improvement in the beneficiary's financial condition, the debt may be deemed uncollectible without the provider having to collect the unpaid Medicare cost sharing liability from beneficiaries by applying the requirements set forth in PRM § 310 for non-indigent beneficiaries.

Over the past several years, the criteria set forth in PRM § 312 regarding the determination of indigence have been the subject of litigation as questions have been raised as to whether the criteria are mandatory. In the proposed rule, we proposed to clarify and codify our longstanding policy and criteria set forth in PRM § 312 A. through D. (setting for the requirements for a facility's determination of indigency).

Stakeholders have questioned why PRM § 312.B requires that the beneficiary's total resources be considered when a provider evaluates a beneficiary's indigence. We believe that each beneficiary's unique total resources must be evaluated to determine whether a beneficiary is indigent. This evaluation must include, but is not limited to, an analysis of assets (only those convertible to cash, and

unnecessary for the beneficiary's daily living), liabilities, and income and expenses, as well as any extenuating circumstances that would affect the determination of the beneficiary's indigence.

Therefore, we proposed to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii) to define an indigent non-dual eligible beneficiary as a Medicare beneficiary who is determined to be indigent by the provider and not eligible for Medicaid as categorically or medically needy. We also proposed to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii)(A) to specify that to determine a beneficiary to be an indigent non-dual eligible beneficiary, the provider must apply its customary methods for determining whether the beneficiary is indigent under the following requirements: (1) The beneficiary's indigence must be determined by the provider, not by the beneficiary; that is, a beneficiary's signed declaration of their inability to pay their medical bills and/or deductibles and coinsurance amounts cannot be considered proof of indigence; (2) the provider must take into account a beneficiary's total resources which include, but are not limited to, an analysis of assets (only those convertible to cash and unnecessary for the beneficiary's daily living), liabilities, and income and expenses. While a provider must take into account a beneficiary's total resources in determining indigence, any extenuating circumstances that would affect the determination of the beneficiary's indigence must also be considered; and (3) the provider must determine that no source other than the beneficiary (for example, a legal guardian) would be legally responsible for the beneficiary's medical bill.

We also proposed to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii)(B) to specify that as part of its determination of indigence, the provider must maintain and furnish, upon request to its Medicare contractor, documentation (for example, a Policy for Determination of Indigence) describing the method by which indigence or medical indigence is determined and the beneficiary-specific documentation which supports the provider's documentation of each beneficiary's indigence or medical indigence. Once indigence is determined and the provider concludes that there has been no improvement in the beneficiary's financial status, the bad debt may be deemed uncollectible without applying a collection effort. Unpaid deductible and coinsurance amounts without the provider's documentation of its determination of indigence will not be considered as allowable bad debts.

We proposed that these revisions would be effective for cost reporting periods beginning before, on and after the effective date of this rule because they are clarifications and codifications of longstanding Medicare policies.

Comment: Some commenters were supportive of the codification of the definition for an indigent non-dual eligible beneficiary because it would provide clarity to the Medicare bad debt policies. Other commenters suggested that the codification of the definitions for each beneficiary category may cause confusion and questioned whether there could be an instance when a beneficiary moved from a non-indigent beneficiary category to an indigent beneficiary category. Some commenters suggested that the codification of the definition for an indigent non-dual eligible beneficiary did not serve an important interest and should not be applied retroactively.

Response: We appreciate the commenters' comments and perspectives. Our longstanding Medicare bad debt rules requiring a provider's reasonable collection effort are different for the three categories of: Beneficiaries who are non-indigent; beneficiaries who have been determined by the provider to be indigent (including medically indigent); or beneficiaries enrolled in Medicaid. Therefore, we believe that as we clarify and codify these longstanding bad debt policies, it is important to set forth the definition of each of these beneficiary categories so that it is clear which bad debt collection effort policies applied to each. A beneficiary's status can change from non-indigent to ''provider-determined indigent'' status during the cost reporting period, or the beneficiary could be enrolled in Medicaid; the provider's required reasonable collection effort is different for each category. We believe that we are promoting the public interest with the retroactive codification of the definition for an indigent non-dual eligible beneficiary. This definition serves to provide clarity because the definitions for this beneficiary category have existed implicitly in the longstanding bad debt collection effort policies that applied to them. We believe that providers will not be burdened or harmed by the application and formalization of a label and definition for a non-indigent beneficiary and an indigent non-dual eligible beneficiary.

Comment: Many commenters opposed the proposal to codify Medicare's longstanding bad debt policy with respect to a provider's determination of a patient's indigence by the required evaluation of a patient's total resources, including a patient's assets, income, expenses and liabilities. Many commenters suggested that only a patient's income be considered when determining whether a patient is indigent and also suggested that an evaluation of a patient's assets, liability and expenses requires additional resources and burden to the provider. Some commenters suggested that an evaluation of a patient's liabilities and expenses only serves to further qualify a patient as indigent. Some commenters questioned why additional parameters were required to evaluate a patient's indigence when the PRM sets forth that providers should apply its customary methods for determining the indigence of patients. Other commenters cited federal court decisions and objected to the proposal to require providers to evaluate assets, income, liabilities and expenses because some viewed the language in the PRM as suggestive requirements and not mandatory. Many commenters opposed the retroactive codification of this policy as proposed.

Response: We appreciate the commenters' varied views on the longstanding Medicare bad debt indigence policies. In the proposed rule, we proposed to codify Medicare's longstanding bad debt policy that requires providers to evaluate a beneficiary's financial status to determine whether the beneficiary can be deemed to be indigent by the provider, permitting the provider to forgo the process to collect a beneficiary's unpaid deductible and coinsurance amounts. In this regard, a provider can deem a beneficiary indigent or medically indigent when the beneficiary has also been determined eligible for Medicaid. If the beneficiary has not been determined eligible for Medicaid, then the provider applies its customary methods for determining indigence under certain guidelines. Our longstanding policy has been that those guidelines require a provider to take into account the beneficiary's total resources to include the consideration of a beneficiary's assets, income, liabilities and expenses. Upon further review and consideration of the comments, we understand that reviewing a patient's liabilities and expenses may not be beneficial in instances when the beneficiary has already qualified for indigence upon evaluation of the beneficiary's income and assets because an evaluation of a beneficiary's liabilities and expenses would only reduce the income and

assets, which serves to further ensure a beneficiary's indigence determination. However, we do not agree, as some commenters suggest, that only a beneficiary's income, but not assets, should be evaluated for indigence for Medicare bad debt purposes. It is possible that a Medicare beneficiary may have assets that are convertible to cash, unnecessary for the beneficiary's daily living, and that can be used for the beneficiary's care, including medical cost sharing expenses. Therefore, we believe that evaluating a beneficiary's income and assets yields a more appropriate assessment of indigence. In circumstances in which a beneficiary may not qualify as financially indigent based on a review of assets and income alone, because their income is too high or their assets too great, a further review of the beneficiary's liabilities and expenses may serve to qualify them for a medical indigence status. Finally, we have reviewed the federal court decisions cited in some comments and do not agree that they prevent us from adopting the rules regarding total resources that we are finalizing.

Comment: Some commenters suggested that providers be permitted to use presumptive eligibility tools, such as those used to qualify patients for federal, state and local uncompensated care or charity care programs, to qualify Medicare beneficiaries for indigence determinations for Medicare bad debt purposes.

Response: We appreciate the commenters' suggestions to allow providers to determine Medicare beneficiaries to be indigent by using presumptive eligibility tools for Medicare bad debt purposes, which could also serve to reduce burden to providers when evaluating indigence. Commenters suggested that many presumptive eligibility tools utilize various factors to evaluate a patient's ability to pay for medical services, including but not limited to, a patient's demographics, zip code, credit score, or income, and could also be used to determine a Medicare beneficiary to be indigent for bad debt purposes. Although presumptive eligibility tools may reduce a provider's burden when evaluating indigence, we disagree that presumptive eligibility tools should be used to determine a Medicare beneficiary's indigence status for Medicare bad debt purposes. Many of the presumptive eligibility tools cursorily review a patient's financial status, based either on the patient's declaration or demographic presumptions, or income and presume one to be indigent. Because we understand that an assessment of a beneficiary's liabilities and expenses may serve to qualify a beneficiary for indigence, we believe that it is appropriate to allow a provider flexibility to consider a beneficiary's extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence, which may include an analysis of the beneficiary's liabilities and expenses, if indigence cannot be determined with a review of the beneficiary's income and assets only.

Comment: Commenters asserted that the proposal to codify the Medicare bad debt indigence evaluation criteria contradicts terms of indigence policies from other programs, such as the National Health Service Corps program, that commenters assert, do not permit providers to inquire about a patient's assets, liabilities, or expenses, and therefore a provider's compliance with Medicare bad debt indigence policy would adversely cause providers to be non-compliant with other indigent policies.

Response: We appreciate commenters' concerns, however we respectfully disagree that a provider's compliance with Medicare bad debt indigence criteria for Medicare beneficiaries precludes providers from participating in other indigence programs. We believe that a provider's compliance with Medicare bad debt indigence policy, in order to qualify a Medicare beneficiary as indigent and claim a Medicare bad debt which is paid from the Medicare Trust Fund, is separate and apart from a provider participating in, or qualifying patients for, other indigence programs that may have different indigence program criteria. As commenters indicate, other Federal, state or local indigent programs may have criteria different from the Medicare bad debt indigence policy, for various reasons or program incentives, and permit providers to use presumptive eligibility tools, to qualify patients for other indigent program. The Medicare bad debt policy is not an indigence program; it is a Medicare policy to pay providers for a beneficiary's unreimbursed deductible and coinsurance amounts after the provider has met certain criteria. The criteria for other indigence programs, such as charity care, may have different program or policy requirements than Medicare bad debt. Medicare does not pay providers directly for charity care, whereas Medicare bad debt amounts may be allowable, and directly paid to various provider types, without the providers performing a reasonable collection effort if the beneficiary qualifies for indigence. As previously stated, we believe it is possible that a Medicare beneficiary may have assets that are convertible to cash, unnecessary for the beneficiary's daily living expenses, which can be used for the beneficiary's care, including medical cost-sharing expenses. Therefore, we believe that evaluating a beneficiary's income and assets yields a more appropriate assessment of indigence for Medicare bad debt purposes. As stewards of the Medicare Trust Fund, CMS must ensure that providers comply with Medicare program policy in order to receive payment for bad debt for Medicare beneficiaries determined to be indigent under Medicare's indigence bad debt policy criteria.

Comment: Some commenters questioned what a provider would need to do to conclude ''that there has been no improvement in the beneficiary's financial status'' once indigence is determined before the bad debt may be deemed uncollectible without applying a collection effort as proposed in § 413.89(e)(2)(ii)(B). Some commenters suggested that this phrase in the proposed regulation text requires additional actions by providers and is vague and burdensome.

Response: We appreciate commenters' concerns. Longstanding Medicare bad debt policy, as published in the PRM § 312, has always required that ''once indigence is determined and the provider concluded that there had been no improvement in the beneficiary's financial condition, the debt may be deemed uncollectible without applying the § 310 procedures.'' We agree with providers that this proposed codification may not be beneficial to providers as it requires providers to take additional actions which may be burdensome, and not produce a different result, once the provider has determined the beneficiary to be indigent under proposed § 413.89(e)(2)(ii)(A). We believe that providers should be afforded more flexibility when determining a beneficiary's indigence and that an analysis of liabilities and expenses should be reviewed in situations where it is only necessary to do so if the beneficiary does not first qualify for indigence with an analysis of income and assets. We also believe that flexibility should be afforded to providers so that they do not have to continually review a beneficiary's financial condition once indigence is determined. However, we recognize that a beneficiary's financial condition may improve, resulting in a change in the beneficiary's indigence status from indigent to non-indigent. If a provider discovers that the beneficiary's financial

condition has improved following the provider's determination of indigence, we expect the provider will no longer classify the beneficiary as indigent and implement reasonable collection efforts for the non-indigent beneficiary.

After consideration of the public comments we received, we are finalizing Medicare bad debt indigence policies applicable to indigent non-dual eligible beneficiaries by amending § 413.89(e)(2) by adding new paragraph (e)(2)(ii) to define an indigent non-dual eligible beneficiary as a Medicare beneficiary who is determined to be indigent by the provider and not eligible for Medicaid as categorically or medically needy. We are not finalizing our proposal to add new paragraph (e)(2)(ii)(A), which would have required a provider to evaluate a beneficiary's liabilities and expenses to determine indigence. Instead, new paragraph (e)(2)(ii)(A) specifies that in order to conclude that a beneficiary is an indigent non-dual eligible beneficiary, the provider: (1) Must not use a beneficiary's declaration of their inability to pay their medical bills or deductibles and coinsurance amounts as sole proof of indigence or medical indigence, (2) Must take into account the analysis of both the beneficiary's assets (only those convertible to cash and unnecessary for the beneficiary's daily living) and income, (3) May consider extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence which may include an analysis of both the beneficiary's liabilities and expenses, if indigence is unable to be determined under (ii)(A)(2), (4) Must determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill, such as a legal guardian or State Medicaid program, and (5) Must maintain and, upon request, furnish its Medicare contractor with the provider's indigence determination policy describing the method by which indigence or medical indigence is determined and all the verifiable beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence. We believe that this policy finalization will reduce burden to providers when determining a beneficiary's indigence. We will evaluate the burden estimates for the recordkeeping requirements in all applicable cost reports, such as OMB Control No. 0938–0050 (Hospitals and Health Care Complex Cost Report), and if these recordkeeping activities have not been accounted for we will revise the ICR(s) via a Paperwork Reduction Act notice. We are not finalizing our proposal to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii)(B), as proposed, to require that once indigence is determined and the provider concludes that there has been no improvement in the beneficiary's financial status, the bad debt may be deemed uncollectible without applying a collection effort. Instead, we are amending § 413.89(e)(2) by adding new paragraph (e)(2)(ii)(B) to specify that once indigence is determined, the bad debt may be deemed uncollectible without applying a collection effort. Unpaid deductible and coinsurance amounts without the provider's documentation of its determination of indigence will not be considered as allowable bad debts. We believe that this policy finalization will reduce burden to providers when determining a beneficiary's indigence.

In the proposed rule, we proposed that our proposals would be effective for cost reporting periods beginning before, on and after the effective date of this rule because our proposals were clarifications and codifications of longstanding Medicare policies. However, because of the changes to the policies we are finalizing after consideration of public comments, we are finalizing these policies with an effective date for cost reporting periods beginning on or after October 1, 2020.

c. Reasonable Collection Effort, Dual Eligible Beneficiaries and the Medicaid Remittance Advice

Dual eligible beneficiaries are Medicare beneficiaries who are enrolled in Medicare (either Part A, Part B, or both), and are also enrolled in ''full Medicaid'' coverage and/or the Medicare Savings Program (MSP).[517] Authorized under sections 1902(a)(10)(E) and 1905(p) and (s) of the Act, the MSP includes four mandatory Medicaid eligibility groups that assist low income Medicare beneficiaries with their Medicare expenses.[518] One specific category of MSP is the Qualified Medicare Beneficiaries (QMB) program. Under 1905(p)(1) of the Act, a QMB is an individual who is entitled to hospital insurance benefits under Part A of Medicare, with income not exceeding 100 percent of the Federal poverty level, and resources not exceeding three times the Supplemental Security Income limit.

Section 1902(a)(10)(E) of the Act directs State Medicaid Agencies to pay providers for QMB cost sharing amounts as defined in section 1905(p)(3) of the Act. Under section 1905(p)(3) of the Act, ''Medicare cost sharing'' includes costs incurred with respect to a QMB, ''without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under the plan.'' The ''Medicare cost sharing'' includes Medicare Part A and B coinsurance and deductibles. Section 1902(n)(2) of the Act permits the State to limit payment for QMB cost sharing to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid, required nominal Medicaid copayments, and third party payments) equal to the amount a State would have paid for the service under the State plan.

State Medicaid Management Information Systems (MMIS), funded under section 1903(a)(3) of the Act, are required, as an express condition of a State receiving enhanced federal matching funds for the design, development, installation and administration of their MMIS systems, to process Medicare crossover[519] claims, including QMB cost sharing, for adjudication of Medicaid payment of Medicare cost sharing amounts, including deductibles and coinsurance for Medicare services. The MMIS is also required to furnish the provider with a Medicaid remittance advice (RA), a document that outlines the State's cost sharing liability for a particular service or set of services for the patient/beneficiary.[520] The Medicaid RA will also show whether the State has no liability for Medicare cost sharing for a beneficiary's service pursuant to the State plan.[521] The MMIS must process all Medicare crossover claims for QMBs, including Medicare-adjusted claims that

[517] ''Full Medicaid'' coverage refers to the package of services, beyond coverage of Medicare premiums and cost-sharing, that certain individuals are entitled to when they qualify under eligibility groups covered under a state's Medicaid program.

[518] The MSP includes the Qualified Medicare Beneficiary, Specified Low-Income Medicare Beneficiary Qualifying Individual, and Qualified Disabled and Working Individual programs. Depending upon the MSP group the individual is enrolled in, the MSP pays all or some of an individual's Medicare expenses, including Parts A and B premiums, deductibles, coinsurance and copayments.

[519] ''Crossover'' claims are initiated when a Medicare certified provider submits a claim to its Medicare contractor for processing of the Medicare covered service and the claim ''crosses over'' to Medicaid for the State to determine and set forth the State's cost sharing liability towards beneficiaries' Medicare cost sharing. This crossover claim includes the primary payment amount from Medicare.

[520] *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-07-2013.pdf.*

[521] *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-07-2013.pdf.*

are submitted by Medicaid-enrolled providers, even if a service or provider category is not currently recognized in the Medicaid State Plan. However, we recognize that there may be instances where the Medicare crossover claim process does not occur automatically, and providers must instead submit their Medicare claims manually to Medicaid for adjudication and determination of the state's cost sharing liability. The most direct and logical way to know a State's cost sharing liability for a QMB is from the Medicaid RA. If a State Medicaid program had Medicare cost sharing responsibility and refused to pay, or failed to process a Medicare crossover claim to determine its cost sharing liability, it would be out of compliance with its Medicaid State plan and would be subject to enforcement action by CMS.

A State's requirement to determine its cost sharing liability for QMBs was also set forth at section 3490.14(A) of the State Medicaid Manual (SMM) (CMS Pub. 45); Payment of Medicare Part A and Part B Deductibles and Coinsurance—State Agency Responsibility, when paper claims were submitted by Medicare providers to the State to determine its cost sharing liability. Specifically, section 3490.14(A)(l) and (2) of the SMM required the State Agency to provide, through the State Plan, the payment rates applicable for services that are either covered or not covered by the State Plan, in order to determine the amount of Medicare coinsurance and deductibles that the State was responsible to pay. Because a QMB's financial situation and Medicaid eligibility status may change over the course of a very short period of time and the State is required to maintain the most current patient eligibility and financial information, the State is in the best position to fulfill its statutory requirement and make the most accurate determination of its cost sharing liability for any unpaid Medicare deductibles and coinsurance.

Providers are prohibited under section 1902(n)(3) of the Act from seeking to collect payment from a QMB for Medicare deductibles or coinsurance, even if the Medicaid State plan's cost sharing liability is less than the total amount of the Medicare deductibles and coinsurance. Medicare may reimburse providers who provide Medicare covered services to dual eligible beneficiaries the difference between beneficiaries' unpaid Medicare cost sharing and the State's Medicare cost sharing liability for the beneficiary, up to the allowable Medicare bad debt amount if the provider has made a reasonable collection effort. To satisfy the reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. A provider satisfies this by billing the State or State designee such as a Medicaid managed care organization (MCO), to determine any Medicare cost sharing amounts for which the State may be liable to the provider. This is known as the ''must-bill policy'' for dual eligible beneficiaries and is outlined in PRM §§ 312 and 322.

In accordance with PRM § 312, providers seeking Medicare reimbursement for bad debts for dual eligible beneficiaries' cost sharing are required to: (1) Bill the State Medicaid program to determine that no source other than the patient would be legally responsible for the patient's medical bill; for example, title XIX, local welfare agency and guardian (the ''must bill requirement''); and (2) obtain and submit to the Contractor, a Medicaid RA from the State Medicaid program (the ''RA requirement''). The must-bill policy and the RA requirement to document the States' cost sharing liability are both longstanding policies of CMS, as shown in PRM §§ 312 and 322 themselves: Administrative decisions applying the policies; and section 4499, exhibit 15.08 of the Medicare Intermediary Manual (CMS Pub. 13–4) (December 1985).

It has always been our position that the must-bill policy and the RA requirement are necessary to ensure that the provider obtains contemporaneous documentation that can be maintained in the usual course of the provider's business as required by § 413.20(a). The historical background of the RA requirement is also set forth in PRM § 322, Medicare Bad Debts Under State Welfare Programs.

Thus, when Medicare certified providers provide services to QMBs and claim bad debt to Medicare for unpaid cost sharing amounts, Medicare bad debt policy requires providers to bill the State and submit to their contractors the Medicaid RA as documentation to evidence the State's liability for dual eligible beneficiaries' deductible and/or coinsurance amounts. If a provider does not bill the State and submit the Medicaid RA to Medicare with its claim for bad debt reimbursement for dual eligible beneficiaries, the result is that unpaid deductible and coinsurance amounts cannot be included as an allowable Medicare bad debt.

In 2003, the Medicare ''must bill'' and RA requirements were upheld by the 9th Circuit Court of Appeals in *Community Hospital of the Monterey Peninsula* v. *Thompson,* 323 F.3d 782 (9th Cir. 2003). In August 2004, CMS issued a Joint Signature Memorandum (''JSM'') 370, reiterating the ''must bill'' policy for dual eligible beneficiaries. Specifically, the JSM 370 reiterated that where the State owes none or only a portion of the dual eligible beneficiary's deductible or coinsurance, the unpaid cost sharing for the beneficiary is not reimbursable to the provider by Medicare until the provider bills the State, and the State refuses payment by producing a Medicaid RA.

In October 2004, we issued a newsletter that reiterated and clarified the contents of the JSM by stating that in instances where the State owes none or only a portion of the dual eligible patient's deductible or copayment, the unpaid liability for the bad debt is not reimbursable to the provider by Medicare until the provider bills the State, and the State refuses payment (with a State Remittance Advice).

In order to satisfy the regulatory requirement that a bad debt is uncollectible, the provider must bill the State Medicaid Agency and receive a Medicaid RA that contains a formal denial from the State or a statement setting forth the State's cost sharing liability. A State's failure to process a bill for determination of its cost sharing equates to a provider's failure to determine the cost sharing liability of the State. The burden remains on the provider to work with the State to determine the State's cost sharing amounts. This burden is not transferred to the Medicare program, and the Medicare program has no duty to determine a State's cost sharing liability. A provider cannot substitute an estimate of the State's cost sharing liability for the Medicaid RA, as this does not satisfy the regulatory requirement of demonstrating that the bad debt is uncollectible. Any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, will not be included as an allowable Medicare bad debt, regardless of whether the State actually pays its obligated amount to the provider. However, the deductible and/or coinsurance amount, or any portion thereof, that the State is not obligated to pay and which remains unpaid by the beneficiary can be included as an allowable Medicare bad debt.

Prior to the implementation of automated claims processing, section

3490.14(B) of the SMM previously provided a mechanism whereby providers could bill the State for the determination of the State's cost sharing amounts without actually being or becoming a Medicaid provider. In accordance with section 3490.14(B), ''Subject to State law a provider has the right to accept a patient either as private pay only, as a QMB only, or (if the patient is both a QMB and Medicaid eligible) as a full Medicaid patient, but the provider must advise the patient, for payment purposes, how he/she is accepted. Medicaid payment of Medicare deductible and coinsurance amounts may be made only to Medicaid participating providers, even though a Medicare service may not be covered by the Medicaid State plan. A provider agreement necessary for participation for this purpose (for example, for furnishing the services to the individual as a QMB) may be executed through the submission of a claim to the Medicaid agency requesting Medicaid payment for Medicare deductibles and coinsurance for QMBs.'' Although this SMM provision is no longer in effect, we believe State Medicaid Agencies have a statutory obligation to determine any Medicare cost sharing for QMBs, however some States do not recognize certain Medicare provider types or services under the State Medicaid program and do not process Medicare crossover claims and issue a Medicaid RA.

Some States' noncompliance with the statutory requirement to process Medicare crossover claims and produce a Medicaid RA have resulted in numerous appeals filed by providers whose claims for reimbursement of unpaid Medicare cost sharing from services provided to dual eligible beneficiaries were denied for Medicare bad debt reimbursement because the State did not process the Medicare crossover claim and issue a Medicaid RA to the provider.

In 2013, CMS attempted to address States' non-compliance with the Federal statutory requirements at sections 1902(a)(10)(E), 1902(n) and 1903(a)(3) of the Act, by issuing an Informational Bulletin,[522] which reminded States of the Federal statutory requirement to process Medicare cost sharing claims for QMBs from Medicare-certified providers, and to be able to document proper processing of such claims. A State's non-compliance with the Federal statutory requirements conflicts with Medicare's must bill policy, resulting in the State's non-compliance and leaving providers disadvantaged.

We continue to believe that the best documentation to evidence States' cost sharing liability for a dual eligible beneficiary is the Medicaid RA, and that the Medicare requirements for the provider to bill the State and submit the RA to its contractor should remain. Where the State processes a Medicare crossover claim and issues a Medicaid RA to the provider that details the State's Medicare cost sharing liability, we believe that providers must continue to provide the Medicaid RA in order to claim Medicare bad debt. Therefore, we proposed that the provider must bill that State and submit the Medicaid RA to Medicare to evidence the State's Medicare cost sharing liability, so that any State Medicare cost sharing liability can be deducted from the Medicare bad debt reimbursement.

Consistent with this proposal, we proposed to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(iii) to clarify and codify that that, effective for cost reporting periods beginning on and before the effective date of this rule, to be considered a reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. To make this determination, the provider must submit a bill to its Medicaid/title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance. (This is effectuated by the provider submitting a bill to Medicare for payment and the MAC administering the payment process automatically 'crosses over' the bill to the applicable Medicaid/title XIX agency for determination of the State's obligation, if any, toward the cost sharing.) The provider must then submit to its contractor a Medicaid RA reflecting the State's payment decision. Any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, will not be included as an allowable Medicare bad debt, regardless of whether the State actually pays its obligated amount to the provider. However, the Medicare deductible and/or coinsurance amount, or any portion thereof that the State is not obligated to pay, can be included as an allowable Medicare bad debt. A provider's failure to bill the State and produce to its Medicare contractor documentation, including the RA reflecting the State's verification that it processed a bill to determine its liability, will result in unpaid deductible and coinsurance amounts not being included as an allowable Medicare bad debt. Unpaid deductible and coinsurance amounts without collection effort documentation will not be considered as allowable bad debts.

We proposed that these revisions be effective for cost reporting periods beginning before, on and after the effective date of this rule because they clarify and codify our longstanding policy to require that the provider effectuate a reasonable collection effort by billing the party (state) responsible for the Medicare cost sharing of the beneficiary. The result of the provider billing the State and the State processing the Medicare crossover claim is the provider's receipt of the Medicaid RA which is necessary to evidence the State's Medicare cost sharing liability.

Although the best documentation to evidence a State's Medicare cost sharing liability for a dual eligible beneficiary is the Medicaid RA, we acknowledged that challenges exist for providers when States do not comply with the Federal statutory requirements. So as not to disadvantage providers in States that are not in compliance with the Federal statute, we considered alternatives for providers to comply with the ''must bill'' policy and still evidence a State's cost sharing liability (or absence thereof) for dual eligible beneficiaries when a State does not process a Medicare crossover claim and issue a Medicaid RA to providers that could be finalized in the final rule. For example, alternative documentation to a Medicaid RA could be obtained by providers from a State that demonstrates it will not enroll the provider in Medicaid, or a certain class of a type of provider, for the limited purpose of processing a claim for determining cost sharing liability. Providers could obtain alternative documentation to a RA such as a State Medicaid notification where the State has no legal obligation to pay the beneficiary's Medicare cost sharing. In a State that has a Medicare cost sharing liability for a beneficiary's service, the Medicaid State Plan may set forth the Medicare cost sharing liability for particular services. Alternatively, in a State that has a Medicare cost sharing liability for a beneficiary's service, the provider could obtain alternative documentation to a Medicaid RA that sets forth the State's Medicare cost sharing liability that would then be deducted from the provider's Medicare bad debt reimbursement. In addition to verifying the state's cost sharing liability, it will also be important that

[522] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-07-2013.pdf.*

any alternative documentation to a Medicaid RA accurately verifies a beneficiary's eligibility for Medicaid for the date of service. We stated that we would consider adopting a policy in this final rule to the effect that when a State does not process a Medicare crossover claim and issue a Medicaid RA, the provider could obtain, and submit to its Medicare contractor, some form of alternative documentation to evidence a state's Medicare cost sharing liability (or absence thereof). We welcomed suggestions from stakeholders regarding the best alternative documentation to the Medicaid RA that a provider could obtain and submit to Medicare to evidence a beneficiary's Medicaid eligibility for the date of service and the State's Medicare cost sharing liability (or absence thereof) and regarding whether we should or could adopt such a policy effective for past cost reporting periods, including whether doing so would serve an important public interest by allowing providers with cases currently pending before the PRRB an avenue for timely and cost-effective resolution.

Comment: Many commenters asserted that CMS lacks the statutory authority to retroactively codify the Medicare bad debt must bill policy applicable to dual eligible beneficiaries and also asserted that the Bad Debt Moratorium prevents retroactive codification. Some commenters asserted that applying Medicare bad debt policies retroactively would create confusion among providers causing providers to request reopening of prior years' cost reports. Some commenters were supportive of the codification of the Medicare bad debt must bill policy applicable to dual eligible beneficiaries.

Response: We respectfully disagree with commenters' assertions that CMS lacks statutory authority to retroactively codify the reasonable collection effort, must bill policy, for dual eligible beneficiaries. The must bill policy is based on a combination of regulatory and sub-regulatory rules that existed for many years prior to the 1987 Bad Debt Moratorium, as explicitly articulated not only in those pre-moratorium rules themselves but also in final agency adjudicatory decisions. We have asserted for many years, based on rules promulgated prior to the moratorium, that Medicare will not reimburse a provider for dual eligible beneficiaries' unpaid deductible and coinsurance amounts unless the provider has first billed the relevant state Medicaid agency and obtained from the state a determination of the state's payment responsibility for the beneficiary's unpaid deductible and coinsurance amounts. Several federal courts have agreed with that position, including the court in *Community Hospital of the Monterey Peninsula* as previously discussed. The court there not only upheld both the must-bill and RA policies as compliant with the moratorium, but indeed struck down our attempt to liberalize the RA requirement while the moratorium was in effect. On several other occasions courts have found that our must-bill and/or RA requirements predated the moratorium. *See Mercy Gen'l Hosp.* v. *Price,* No.16–99, 2017 WL 4797796 (D.D.C. 2017) (Mag. Report and Recommendation) (must-bill and RA requirements predate the moratorium); *Mercy Gen'l Hosp.* v. *Azar,* 410 F. Sup.3d 63 (D.D.C. 2019) (must-bill requirement predates the moratorium); *Select Specialty Hosp.-Denver, Inc.* v. *Azar,* 391 F. Supp.3d 53 (D.D.C. 2019) (must-bill requirements has been consistently articulated since at least 1983). We reject the commenters' suggestion that we are not now merely clarifying and codifying our longstanding must-bill and RA requirements for the reasons stated in these cases. To the extent any of these cases suggest the RA requirement did not predate the moratorium, we disagree with such a characterization. At least one agency adjudication involving cost years predating the moratorium articulates the requirement that a provider obtain a state determination of its payment obligation before claiming bad debt reimbursement from Medicare. *See Hosp. de Area de Carolina* v. *Coop. de Seguros de Vida de Puerto Rico,* PRRB No. 93–D23, CCH ¶ 41,411 (HCFA Ad. 1993).

Some commenters cited *Bowen* v. *Georgetown Univ. Hosp.,* 488 U.S. 204, 208 (1988), as showing that CMS lacked statutory authority to retroactively codify our longstanding Medicare bad debt policies. In *Georgetown,* the Supreme Court of the United States held that the APA did not grant federal agencies the statutory authority to promulgate rules retroactively, but noted that Congress could bestow that authority in other specific statutory provisions. However, we note that *Georgetown* was decided in 1988, prior to the promulgation of SSA 1871(e)(1) in 2003 which Congress granted CMS the statutory authority to promulgate rules retroactively in certain circumstances, one of which is when the failure to do so would be contrary to the public interest. We believe there is significant public interest served by applying these Medicare bad debt rules retroactively because doing so would provide guidance with certainty and clarity, yielding timely and cost-effective relief to providers with cases currently pending before the PRRB. In this regard, we believe that our failure to codify these rules in a retroactive manner would actually harm providers and be contrary to public interest. While some commenters stated that we misunderstood the statutory standard for promulgating retroactive rules as being whether such promulgation was in the public interest, (not whether failing to do so would be contrary to the public interest), that is not the case. We also reject some commenters' suggestion that applying these rules retroactively would cause rather than alleviate confusion because it might lead to provider requests for reopening of notices of program reimbursement (NPRs). Any such request would only apply to an NPR issued within three years before the request. Moreover, CMS has almost total discretion to deny a request for reopening. For all these reasons, we believe any additional confusion or burden imposed in connection with reopening requests prompted by retroactive application of these rules would be minimal. We continue to believe that on balance applying these rules retroactively will promote rather than impede clarity and understanding of the applicable rules by providers, beneficiaries, our contractors, and other stakeholders. To the extent commenters assert that our bad debt policies have been subject to varying interpretations or the subject of litigation, that is a factor in favor of clarifying them retroactively, not one against it.

Comment: Some commenters asserted that the bad debt must bill policy applicable to dual eligible beneficiaries did not serve an important interest for a dual eligible beneficiary's Medicare cost sharing because they assert that states pay little, if anything, toward a dual eligible beneficiary's Medicare cost sharing and thus, billing the state Medicaid agency was not a worthwhile exercise. Some commenters noted that the crossover billing process sometimes fails for other various reasons.

Response: We disagree with commenters' conclusions that the Medicare bad debt must-bill policy does not serve an important interest to ascertain the states' cost sharing liability for dual eligible beneficiaries. As noted earlier, we continue to believe that the best documentation to evidence States' cost sharing liability for a dual eligible beneficiary is the Medicaid RA, produced by the state following its claim by claim adjudication of the Medicare crossover billing. Amounts

that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, will not be included as an allowable Medicare bad debt and thus are amounts that are not paid from the taxpayer funded Medicare Trust Fund. As stewards of the Medicare Trust Fund, CMS is obligated to manage the Medicare Trust Fund in a fiscally prudent manner which entails ensuring accurate amounts are paid therefrom. If the Medicare crossover billing fails or is not completed in certain instances when submitted as a matter of course in the crossover claims process, the provider has opportunity to work with the Contractor to identify and resolve the issue.

Comment: Many commenters were supportive of a policy whereby providers can submit alternate documentation to a Medicaid RA in instances where the State fails to issue the provider a Medicaid RA that evidences the State's Medicare cost sharing liability for a dual eligible beneficiary, however some commenters expressed disappointment that a specific proposal for alternate documentation was not set forth in the proposed rule. Some commenters were not supportive of a resolution that would be applied retroactively. Some commenters suggested that submission of alternate documentation be permitted, similar to what was previously set forth in the now obsolete section 1102.3L of the PRM, Part 2 manual provision, that required submission of evidence the beneficiary was eligible for Medicaid on the date of service, copies of billing for the Medicare cost sharing amounts that were sent to the State Medicaid Agency, and copies of the Medicaid RA showing the denial and the amounts of the Medicare cost sharing. Other commenters suggested that providers should be allowed to submit, as alternate documentation to the Medicaid RA, the State Medicaid notification evidencing that the State has no legal obligation to pay the beneficiary's Medicare cost sharing, documentation setting forth the State's liability for the Medicare cost sharing, and documentation verifying the beneficiary's eligibility for Medicaid for the date of service. Some commenters suggested that Medicare contractors assist providers in ascertaining the State's Medicare cost sharing liability.

Response: We appreciate commenters' support of the adoption of a policy whereby providers can submit alternate documentation to a Medicaid RA. As previously mentioned, we considered adopting a policy in this final rule to the effect that when a State does not process a Medicare crossover claim and issue a Medicaid RA, the provider could obtain, and submit to its Medicare contractor, some form of alternative documentation to evidence a state's Medicare cost sharing liability (or absence thereof). We welcomed suggestions from stakeholders regarding the best alternative verifiable documentation to the Medicaid RA that would set forth the State's Medicare cost sharing liability. We agree with many commenters' suggestions and believe that the vital items needed to substitute a Medicaid RA must contain all of the following: (1) The State Medicaid notification stating that the State has no obligation to pay the beneficiary's Medicare cost sharing or notification evidencing the provider's inability to enroll in Medicaid for purposes of processing a crossover cost sharing claim, (2) documentation setting forth the State's liability, or lack thereof, for the Medicare cost sharing, and (3) documentation verifying the beneficiary's eligibility for Medicaid for the date of service.

We believe that under (1), as previously detailed, the State's Medicaid notification stating that the State has no legal obligation to pay the provider for the beneficiary's Medicare cost sharing, or documentation evidencing the provider's inability to enroll in Medicaid for purposes of processing a Medicare crossover cost sharing claim, must be through no fault or deficiency of the provider. This means that if the provider could have enrolled as a Medicaid provider, but chose not to do so for reasons such as inconvenience or a business decision, the evidence of non-enrollment would be an impermissible document to accept as an alternate to the Medicaid RA acceptance. However, if the provider was not recognized by the State Medicaid Agency as a Medicaid provider type, then documentation evidencing that the State Medicaid Agency does not recognize the provider as a Medicaid provider type for purposes of processing a Medicare crossover cost sharing claim would be sufficient to evidence the State's notification of no obligation to pay the beneficiary's Medicare cost sharing. We understand that in some states it may be difficult to supply evidence that the state will not enroll a specific provider type. Medicare contractors will have to afford providers flexibility in producing acceptable evidence. We encourage states to consider separate enrollment pathways for Medicare providers that seek to enroll in Medicaid solely for the purposes of processing Medicare crossover claims for dually eligible beneficiaries.

We also believe that under (2), as previously detailed, documentation setting forth the State's liability for the Medicare cost sharing, or lack thereof, can be produced by the provider, in part, from the State Plan documents and may also include other documents such as state and state contractor fee schedules or payment rates, or other documents the provider produces that can be verified by the contractor. We note that the process of documenting the State's liability for Medicare cost sharing may entail a comparison of the Medicare and Medicaid rates for certain services, as well as documentation from the Medicaid State plan on whether the state uses a lesser-of methodology for that service type. We believe that ascertaining the State's cost sharing liability amount may result from a collaborative effort between the provider, state, and the Medicare contractor. Medicare contractors will afford providers flexibility in producing documentation acceptable to evidence the State's Medicare cost sharing in the absence of a Medicaid RA.

Regarding (3), as previously detailed and noted by some commenters, documentation verifying the beneficiary's eligibility for Medicaid for the date of service could take the form of an eligibility report from a state's eligibility verification system. For example, for QMBs the provider can query the CMS HIPAA Eligibility Transaction System (HETS), or for Medicare claims processed on or after October 2, 2017, provide a Medicare remittance advice showing the QMB status.

Medicare contractors will afford providers flexibility in producing acceptable evidence of the beneficiary's eligibility for Medicaid for the date of service. We will work with the providers, states, and Medicare contractors on guidelines for acceptable alternative documentation to the Medicaid RA. We believe that codifying an alternate documentation policy and applying it retroactively will serve an important public policy interest by providing clarity, cost effective relief and burden reduction to providers with cases currently pending before the PRRB.

After consideration of the public comments we received, we are finalizing our proposal to codify our longstanding Medicare must bill bad debt policy with respect to QMB dual eligible beneficiaries to require that the provider must bill the State for the QMB's Medicare cost sharing and

submit the resulting Medicaid RA the provider receives to Medicare to evidence the State's Medicare cost sharing liability, so that any State Medicare cost sharing liability can be deducted from the Medicare bad debt reimbursement. We are also codifying an alternate Medicaid RA documentation policy so that, in limited circumstances, providers can comply with the must bill policy and still evidence a State's cost sharing liability (or absence thereof) for dual eligible beneficiaries when a State does not process a Medicare crossover claim and issue a Medicaid RA to providers. In this regard, we are codifying that to be considered a reasonable collection effort for dual eligible beneficiaries when alternative documentation to the Medicaid remittance advice is submitted, a provider must submit all of the following: (1) The State Medicaid notification evidencing that the State has no obligation to pay the beneficiary's Medicare cost sharing or notification evidencing the provider's inability to enroll in Medicaid for purposes of processing a crossover cost sharing claim, (2) documentation setting forth the State's liability, or lack thereof, for the Medicare cost sharing, and (3) documentation verifying the beneficiary's eligibility for Medicaid for the date of service. These policies are effective for cost reporting periods beginning before, on and after the effective date of this final rule. We will continue to evaluate our alternative Medicaid RA documentation policy so that any policy refinements can be addressed in future rulemaking, if needed. We will instruct contractors to commence a process to work with providers to resolve cases pending before the PRRB so that providers may experience relief and burden reduction through the application of this rule to their existing cases.

d. Accounting Standard Update Topic 606 and Accounting for Medicare Bad Debt

(1) Accounting Standard Update Topic 606

The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program (see § 413.20(a)). Additionally, providers must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the hospital and related fields (see § 413.20(a)). Medicare accounting standards follow the general accounting standards unless the Secretary declares otherwise on a particular matter (see § 413.20(a)). The regulations at § 413.89(c) provide that the normal accounting treatment for bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services. In this regard, providers are required to record bad debts and uncollectible accounts as a direct reduction of net patient revenue rather than an operating expense in their financial records.

Additionally, PRM § 314, ''Accounting Period for Bad Debts'', provides further guidance to providers for the accounting treatment of Medicare bad debts and sets forth that ''Uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless. Allowable bad debts must be related to specific amounts which have been determined to be uncollectible. Since bad debts are uncollectible accounts receivable and notes receivable, the provider should have the usual accounts receivable records-ledger cards and source documents to support its claim for a bad debt for each account included'' (PRM § 314). PRM § 320 sets forth methods of determining bad debt expense, where ''accounts receivable are analyzed and a determination made as to specific accounts which are deemed uncollectible. The amounts deemed to be uncollectible are charged to an expense account for uncollectible accounts. The amounts charged to the expense account for bad debts should be adequately identified as to those which represent deductible and coinsurance amounts applicable to beneficiaries and those which are applicable to other than beneficiaries or which are for other than covered services. Those bad debts which are applicable to beneficiaries for uncollectible deductible and coinsurance amounts are included in the calculation of reimbursable bad debts.''

The Financial Accounting Standards Board's (FASB) Accounting Standards Update (ASU) 2014–09, Revenue from Contracts with Customers (Topic 606), (hereinafter ''ASU Topic 606''), was published in May 2014 with the first implementation period in 2018. Under the ASU Topic 606, there are changes in the national accounting standard for revenue recognition of patient-related bad debts and uncollectible accounts, as well as changes to terminology regarding bad debts. These changes are for all industries and organizations nationwide, including the healthcare sector and providers. Under the ASU Topic 606, an amount representing a bad debt would generally no longer be reported separately as an operating expense in the provider's financial statements, but would generally be treated as an ''implicit price concession,'' and included as a reduction in patient revenue. Additionally, under the ASU Topic 606 standards, bad debts treated as ''implicit price concessions'' are now considered to be ''reductions in patient revenue'' instead of ''uncollectible accounts receivable and notes receivable'' in accordance with the current language in PRM § 316. Additionally, under the ASU Topic 606 standards, the provider should have the usual ''accounting recordations for the reductions in revenue'' instead of ''accounts receivable records ledger cards'' as set forth in the current language in PRM § 316.

Although ASU Topic 606 requires different reporting for providers and terminology for bad debts (also known as implicit price concessions), there is no change in the required criteria a provider must meet to qualify a beneficiary's bad debt account for Medicare bad debt reimbursement under § 413.89. Therefore, we proposed to recognize the ASU Topic 606 terminology in § 413.89. Specifically, we proposed to recognize that bad debts, also known as ''implicit price concessions,'' are amounts considered to be uncollectible from accounts that were created or acquired in providing services. ''Implicit price concessions'' are designations for uncollectible claims arising from the furnishing of services, and may be collectible in money in the relatively near future and are recorded in the provider's accounting records as a component of net patient revenue.

We proposed to amend § 413.89(b)(1) by adding new paragraph (b)(1)(i) to specify that for cost reporting periods beginning before October 1, 2020, bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. ''Accounts receivable'' and ''notes receivable'' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future. Consistent with this proposal, we are also proposing to amend § 413.89(b)(1) by adding new paragraph (b)(1)(ii) to specify that for cost reporting periods beginning on or after October 1, 2020, bad debts, also known as ''implicit price concessions,'' are amounts considered to be

uncollectible from accounts that were created or acquired in providing services. ''Implicit price concessions'' are designations for uncollectible claims arising from the furnishing of services, and may be collectible in money in the relatively near future and are recorded in the provider's accounting records as a component of net patient revenue. We also proposed to amend § 413.89(c) by adding new paragraph (c)(1) to specify that effective for cost reporting periods beginning before October 1, 2020 bad debts, charity, and courtesy allowances represent reductions in revenue. We also proposed to amend § 413.89(c) by adding new paragraph (c)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2020, bad debts, also known as ''implicit price concessions,'' charity, and courtesy allowances represent reductions in revenue.

Comment: Many commenters were supportive of our proposal to adopt the ASU Topic 606 terminology for bad debt to be recognized as an implicit price concession. Some commenters suggested that many of our ASU Topic 606 terminology adoptions have already been adopted by hospitals on their financial statements but have not been incorporated for purposes of the Medicare cost report. Other commenters suggested that the implicit price concession terminology should be incorporated into the Worksheet S–10 for incorporation into uncompensated care calculations. Some commenters suggested a retroactive effective date to coincide with the effective date of ASU Topic 606.

Response: We appreciate commenters' support of our proposals to adopt the ASU Topic 606 terminology for bad debt to be recognized as an implicit price concession, a reduction in revenue. We recognize that under the ASU Topic 606 standards, the provider should have the usual ''accounting recordations for the reductions in revenue.'' We believe that our proposals to include this terminology in the regulatory definition of bad debt are responsive to stakeholders' requests. We agree with commenters' suggestions that the implicit price concession terminology should be incorporated into the Worksheet S–10 for incorporation into uncompensated care calculations. We believe that it is most appropriate to adopt this policy with a future effective date.

We note that we did not propose to adopt this policy retroactively and that providers might or might not have already changed their accounting terminology to coincide with the ASU Topic 606 standards. Nor is the policy we are finalizing a longstanding Medicare policy that we are merely clarifying. As a result, we have not determined that failing to apply this provision retroactively would be contrary to the public interest.

After consideration of the public comments we received, we are finalizing our proposal to amend § 413.89(c) by adding new paragraph (c)(1) to specify that effective for cost reporting periods beginning before October 1, 2020 bad debts, charity, and courtesy allowances represent reductions in revenue. We also finalizing our proposal to amend § 413.89(c) by adding new paragraph (c)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2020, bad debts (also known as ''implicit price concessions)'' charity, and courtesy allowances represent reductions in revenue.

(2) Medicare Bad Debt and Contractual Allowances

Medicare regulations require providers to follow standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields. PRM § 320 sets forth methods of determining bad debt expense, where accounts receivable are analyzed and a determination made as to specific accounts which are deemed uncollectible. The amounts deemed to be uncollectible are charged to an expense account for uncollectible accounts. The amounts charged to the expense account for bad debts should be adequately identified as amounts that represent deductible and coinsurance amounts applicable to Medicare beneficiaries, including QMBs, amounts that are applicable to non-beneficiaries, or amounts that are for other than covered services. Those bad debts which are applicable to Medicare beneficiaries, including QMBs, for uncollectible deductible and coinsurance amounts are included in the calculation of reimbursable bad debts.''

Based on recent questions received, it appears that many providers are not accurate in their accounting classification method of writing-off a beneficiary's deductible and coinsurance amounts for Medicare-Medicaid crossover claims, by incorrectly writing off Medicare-Medicaid crossover bad debts to a contractual allowance account. Contractual allowances, also known as contractual adjustments, are the difference between what a healthcare provider bills for the service rendered versus what it will contractually be paid (or should be paid) based on the terms of its contracts with third-party insurers and/or government programs.[523] Some providers have been writing Medicare-Medicaid crossover bad debt amounts off to a contractual allowance account because they are unable to bill the beneficiary for the difference between the billed amount and the Medicaid claim payment amount. Other providers are writing these amounts off to a contractual allowance account because the Medicaid remittance advice referenced the unpaid amount as a ''Medicaid contractual allowance.'' These Medicare-Medicaid crossover claim amounts do not meet the classification requirements for a Medicare bad debt as set forth in PRM § 320 and are not compliant with § 413.20 when these amounts are written off to a contractual adjustment or allowance account instead of a bad debt expense account.

The April 4, 2019 Medicare Learning Network Special Edition (MLN SE) article served to remind providers of Medicare's longstanding policy with regard to the provider's proper reporting of Medicare bad debts for cost reporting periods beginning before October 1, 2019. The MLN SE also served as a notification to providers but also provided flexibility by allowing providers to report contractual allowance amounts as a bad debt, as long as 413.89 requirements are met, for cost reporting periods beginning before October 1, 2019. The MLN SE also served to remind providers of the expectation for proper reporting of Medicare bad debts and that following the flexibility notice period, reporting Medicare bad debts as a contractual allowance was no longer permissible for cost reporting periods on or after October 1, 2019.

In the proposed rule, we proposed to clarify that Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession). Consistent with this proposal, we proposed to amend § 413.89(c) by adding paragraph (c)(3) to specify that, effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession).

Comment: Many commenters were not supportive of the proposed

[523] *https://www.lbmc.com/blog/contractual-allowance-for-healthcare-providers.*

regulation text in § 413.89(c)(3) that ''Effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts.'' Many commenters suggested that the language refer to implicit price concessions instead of bad debt and also that the accounts be charged to ''a reduction in revenue expense account for uncollectible accounts'' instead of ''an expense account for uncollectible accounts.'' Many commenters suggested that the proposal would increase burden to providers by requiring them to change accounting practices and that providers have recorded bad debts in their accounting records as contractual allowances for years citing the Generally Accepted Accounting Principles (GAAP) as the permissive authority to do so. Another commenter indicated that providers classify their Medicare-Medicaid crossover bad debt as contractual allowances and contractors reimburse them for a portion of these contractual allowance amounts. Other commenters suggested a retroactive date to coincide with the effective date of ASU Topic 606, while other commenters did not favor a retroactive effective date. Some commenters questioned whether the effective date for this provision should be October 1, 2019, pursuant to the effective date for which we issued guidance to contractors in a technical direction letter issued in March 2019, regarding the treatment of contractual allowances on the Medicare cost report.

Response: We appreciate the commenters' suggestions. We believe it is necessary to reiterate that it is never appropriate for a provider to write off Medicare-Medicaid crossover bad debt amounts to a contractual allowance account simply because they are unable to bill the beneficiary for the difference between the billed amount and the Medicaid claim payment amount. It is likewise inappropriate to present these amounts to Medicare for reimbursement as Medicare bad debts. We agree with commenters that the proposal to amend § 413.89(c) by adding paragraph (c)(3) to specify that, ''effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession),'' incorrectly refers to an ''expense account'' and should instead more clearly refer to as a ''component of net patient revenue'' or a ''reduction in revenue'' account.

We believe the April 4, 2019 MLN SE article served as a notification to providers and provided flexibility by allowing providers to report contractual allowance amounts as a bad debt, as long as 413.89 requirements are met, for cost reporting periods beginning before October 1, 2019. The MLN SE notification also served to remind providers that compliance with the longstanding Medicare bad debt policy in § 320 of the PRM for cost reporting periods beginning on or after October 1, 2019 is required, so that bad debts are written off to an expense account, and not a contractual allowance account. Because we are now adopting the implicit price concession terminology effective for cost reporting periods beginning on or after October 1, 2020, for Medicare bad debt purposes, the bad debt must be recorded in the provider's accounting records as a component of net patient revenue. We are not codifying this retroactively because we believe that all providers should have equal understanding and footing as we move forward with the standardized definitions, accounting and reporting practices and the intersection with the new implicit price concession standards.

After consideration of the public comments we received, we are revising our proposal to amend § 413.89(c) by adding paragraph (c)(3)(i) to specify that, for cost reporting periods beginning before October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts. We are also revising our proposal to amend § 413.89(c) by adding paragraph (c)(3)(ii) to specify that, for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an uncollectible receivables account that results in a reduction in revenue. We are not applying a retroactive effective date to this proposal for the same reasons as previously discussed regarding the effective date of ASU Topic 606.

e. Technical Corrections in 42 CFR Parts 412 and 417

A technical correction is required for 42 CFR 412.622(b)(2)(i) which incorrectly refers to 42 CFR 413.80 instead of the correct citation of § 413.89, which is the regulation that sets forth rules pertaining to the bad debts of Medicare beneficiaries.

A technical correction is also required for 42 CFR 417.536(g) which incorrectly refers to § 413.80 instead of the correct citation of § 413.89, which sets forth that bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable costs.

We received no comments on the proposal to make technical corrections to the citations in § 412.622(b)(2)(i) and § 417.536(g), and therefore are finalizing these citation corrections without modification.

X. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2020 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2021 are addressed in Appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at: *http://www.medpac.gov*.

XI. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* We listed the data files available in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32876 through 32878).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information

collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the FY 2021 IPPS/LTCH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs Regarding PRRB Electronic Filing (§§ 405.1801 Through 405.1889)

As stated earlier in section IX.B.3 of the preamble of this final rule, we are finalizing our proposal to amend the regulations at 42 CFR 405.1801 through 405.1889 to allow the PRRB to make use of the system mandatory in PRRB appeals. Proposed § 405.1801 states that except for subpoena requests being sent to a nonparty pursuant to § 405.1857(c), the reviewing entity may prescribe the method(s) by which a party must make a submission, including the requirement to use an electronic filing system for submission of documents. Proposed amendments to the regulations at 42 CFR 405.1843 make clear that parties to a Board appeal must familiarize themselves with the instructions for handling a PRRB appeal, including any and all requirements related to the electronic or online filing of documents for future mandatory filing.

The burden associated with the requirements as discussed in this section is the time and effort necessary to review instructions and register for the electronic submission system as well as the time and effort to gather develop and submit various documents associated with a PRRB appeal. While these requirements impose burden, we believe the requirements are exempt from the PRA in accordance with the implementing regulations of the PRA at 5 1320.4(a)(2). Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

3. ICRs for Requests for Changes to the Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications

As discussed in section II.D. of the preamble of this final rule, the public may request changes to the MS–DRG classifications to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The burden associated with requesting changes to the MS–DRG classifications will be discussed in a forthcoming information collection request, which is currently under development. However, upon completion of the ICR, we will publish the required 60-day and 30-day notices to solicit public comments in accordance with the requirements of the PRA.

4. ICRs Relating to the Hospital Readmissions Reduction Program

In section IV.K. of the preamble of this final rule, we note that we did not propose the removal or adoption of any new measures into the Hospital Readmissions Reduction Program. All six of the Hospital Readmissions Reduction Program's measures are claims-based measures. We do not believe that continuing to use these claims-based measures creates or reduces any burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes. We did not receive any comments regarding the ICRs for the Hospital Readmissions Reduction Program and therefore are finalizing without modification.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.L. of the preamble of this final rule, we provide newly established performance standards for the Hospital VBP Program for certain measures for the FY 2023, FY 2024, FY 2025, and FY 2026 program years. We do not believe that updating program performance standards will create or reduce any burden for hospitals. Data submissions for the Hospital VBP Program are associated with the Hospital Inpatient Quality Reporting Program under OMB control number 0938–1022, the National Healthcare Safety Network under OMB control number 0920–0666, and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey under OMB control number 0938–0981. Because the FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this final rule.

Comment: A few commenters expressed their support for the newly established performance standards for certain measures for the FY 2023 through FY 2026 program years.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing this provision without modification.

6. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In section IV.M. of the preamble of this final rule, we discuss proposed requirements for the HAC Reduction Program. In this final rule, we are not removing any measures or adopting any new measures into the HAC Reduction Program. The HAC Reduction Program has adopted six measures. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates or reduces any burden for hospitals because it is collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes. We note the burden associated with collecting and submitting data for the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA bactermia, and CDI) via the NHSN system is captured under a separate OMB control number, 0920–0666 (expiration November 30, 2021), and therefore will not impact our burden estimates.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we finalized our policy to validate NHSN HAI measures under the HAC Reduction Program, which will require hospitals to submit validation templates for the NHSN HAI measures beginning with Q3 CY 2020 discharges. OMB has currently approved these 43,200 hours of burden and approximately $1.6 million under OMB control number 0938–1352 (expiration date January 31, 2021), accounting for information collection burden experienced by up to 600 IPPS hospitals selected for validation under the HAC Reduction Program for the FY 2023 program year and each subsequent year.

In section IV.M.6. of the preamble of this final rule, we finalized changing the pool of hospitals selected for validation under the HAC Reduction Program from up to 600 hospitals to up to 400 hospitals, as similarly proposed under

the Hospital IQR Program, as discussed in section VIII.A. of the preamble of this final rule. In this FY 2021 IPPS/LTCH PPS final rule, we updated our burden calculation to reflect the reduction in the number of hospitals selected for validation each year along with using the most recent data from the Bureau of Labor Statistics that reflects a median hourly wage of $19.40 [524] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour.

We previously estimated a reporting burden of 80 hours (20 hours per record × 1 record per hospital per quarter × 4 quarters) per hospital selected for validation per year to submit the CLABSI and CAUTI templates, and 64 hours (16 hours per record × 1 record per hospital per quarter × 4 quarters) per hospital selected for validation per year to submit the MRSA and CDI templates for a total of 43,200 hours ([80 hours × 300 hospitals] + [64 hours × 300 hospitals]). We estimate a new total burden of 28,800 hours ([80 hours per hospital to submit CLABSI and CAUTI templates × 200 hospitals selected for validation] + [64 hours per hospital to submit MRSA and CDI templates × 200 hospitals selected for validation]), reflecting a total burden decrease of 14,400 hours (43,200 hours − 28,800 hours), and a new total burden cost of approximately $1,117,440 (28,800 hours × $38.80 per hour [525]). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1352. We did not receive any comments regarding the ICRs for the HAC Reduction Program and are therefore finalizing these ICRs without modification.

7. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 1,612,710 hours of burden and approximately $60.7 million under OMB control number 0938–1022, accounting for information collection burden experienced by approximately 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2022 payment determination. In this final rule, we describe the burden changes with regard to collection of information under OMB control number 0938–1022 (expiration date December 31, 2022) for IPPS hospitals due to the finalized proposals in this final rule.

In section VIII.A.5.b. of the preamble to this final rule, we are finalizing a policy to progressively increase the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report two quarters of data for the CY 2021 reporting period/FY 2023 payment determination, three quarters of data for the CY 2022 reporting period/FY 2024 payment determination, and four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We expect these policies will increase our collection of information burden estimates. Details on these policies as well as the expected burden changes are discussed further in this section of this rule.

In section VIII.A. of the preamble to this final rule, we are finalizing the proposal to begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. As discussed further in this final rule, we do not expect this policy to affect our information collection burden estimates.

In section VIII.A.11. of the preamble to this final rule, we also are finalizing proposals to streamline validation processes under the Hospital IQR Program. We are finalizing proposals to: (1) Update the quarters of data required for validation for both chart-abstracted measures and eCQMs; (2) expand targeting criteria to include hospital selection for eCQMs; (3) change the validation pool from 800 hospitals to 400 hospitals; (4) remove the current exclusions for eCQM validation selection, (5) require electronic file submissions for chart-abstracted measure data; (6) align the eCQM and chart-abstracted measure scoring processes; and (7) update the educational review process to address eCQM validation results. As discussed further in this final rule, we expect our finalized proposal to align the hospital selection process will increase our information collection burden estimates. We do not expect the other finalized validation proposals to affect our information collection burden estimates. Details on these policies as well as the expected burden changes are discussed further in this section of this rule.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42602 through 42605), we estimated that reporting measures for the Hospital IQR Program could be accomplished by staff with a median hourly wage of $18.83 per hour. We note that since then, more recent wage data have become available, and we are updating the wage rate used in these calculations in this final rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional.[526] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

b. Information Collection Burden Estimates for Proposed Policies Related to eCQM Reporting and Submission Requirements for the CY 2021 Reporting Period/FY 2023 Payment Determination, the CY 2022 Reporting Period/FY 2024 Payment Determination, and the CY 2023 Reporting Period/FY 2025 Payment Determination and Subsequent Years

In the FY 2020 IPPS/LTCH PPS final rule, we finalized eCQM reporting and submission requirements such that hospitals submit one, self-selected calendar quarter of data for four eCQMs for the CYs 2020 and 2021 reporting periods/FYs 2022 and 2023 payment determinations (84 FR 42503) and one, self-selected calendar quarter of data for three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing

[524] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[526] *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

eCQM for the CY 2022 reporting period/FY 2024 payment determination (84 FR 42505). Our related information collection estimates were discussed at (84 FR 42604).

In sections VIII.A.10.e.(1). through (4). of the preamble to this final rule, we are finalizing our proposal to progressively increase the number of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report: (1) Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination, while continuing to require hospitals to report four self-selected eCQMs; (2) three quarters of data for the CY 2022 reporting period/FY 2024 payment determination, while continuing to report three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM ; and (3) four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years, while continuing to require hospitals to report three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM. We believe there would be a progressive increase to the burden estimate over the 3-year period due to these proposed policies.

We previously estimated the information collection burden associated with the eCQM reporting and submission requirements to be 40 minutes per hospital per year (10 minutes × 4 eCQMs × 1 quarter = 40 minutes), or 0.67 hours per hospital per year (40 minutes/60). We estimated a total annual burden of 2,200 hours across all IPPS hospitals (0.67 hours × 3,300 IPPS hospitals). Using the updated wage estimate as described previously, we estimate this to represent a total annual cost of $85,360 ($38.80 hourly wage × 2,200 annual hours) across all IPPS hospitals. Based on our proposal to progressively increase the number of quarters of data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, we estimate an annual burden increase of 2,200 hours and $85,360 for all participating IPPS hospitals for each of the CY 2021 reporting period/FY 2023 payment determination, CY 2022 reporting period/FY 2024 payment determination, and CY 2023 reporting period/FY 2025 payment determination. By increasing the number of quarters of eCQM data required to be reported by hospitals from one self-selected quarter of data to two quarters of data, then to three quarters of data, and finally to four quarters of data, respectively, we estimate a total increase of 6,600 hours (2,200 hours + 2,200 hours + 2,200 hours) and $256,080 ($85,360 + $85,360 + $85,360) across a 3-year period for all participating IPPS hospitals.

c. Information Collection Burden Estimate for Proposed eCQM Public Display Requirements Beginning With the CY 2021 Reporting Period/FY 2023 Payment Determination

In section VIII.A.13.b. of the preamble to this final rule, we are finalizing a policy to begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. Because hospitals would not have any additional information collection requirements, we believe there would be no change to the information collection burden estimate due to this policy, but acknowledge that there are other types of burden associated with this proposal. For example, there is burden associated with the optional reviewing of hospital-specific reports during the public reporting preview period; however, we believe this burden is nominal because hospitals already review these reports with respect to other types of measures for the Hospital IQR Program.

d. Information Collection Burden Estimate for Proposed Updates to the Processes for Validation of Hospital IQR Program Measure Data

In section VIII.A.11. of the preamble to this final rule, we are finalizing proposals to make several changes to streamline the validation process. We are finalizing our proposals to: (1) Require the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allow the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive, beginning with validation of Q1 2021 data affecting the FY 2024 payment determination; (2) combine the validation processes for chart-abstracted measures and eCQMs by: (a) Aligning data submission quarters, with the validation quarters affecting the FY 2023 payment determination serving as a transition year before being fully aligned as to validation quarters affecting the FY 2024 payment determination; (b) combining hospital selection, including: (i) Reducing the pool of hospitals randomly selected for chart-abstracted measure validation, and (ii) integrating and applying targeting criteria for eCQM validation, beginning with validation affecting the FY 2024 payment determination; (c) removing previous exclusion criteria; and (d) combining scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero, beginning with validation affecting the FY 2024 payment determination; and (3) formalize the process for conducting educational reviews for eCQM validation in alignment with current processes for providing feedback for chart-abstracted validation results, beginning with eCQM validation affecting the FY 2023 payment determination.

As noted in the FY 2017 IPPS/LTCH IPPS final rule (81 FR 57261), we have been reimbursing hospitals directly for expenses associated with submission of medical records for data validation; specifically, we reimburse hospitals at 12 cents per photocopied page; for hospitals providing medical records digitally via a rewritable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we reimburse hospitals at a rate of 40 cents per disc, along with $3.00 per record; and for hospitals providing medical records as electronic files submitted via secure file transmission, we reimburse hospitals at $3.00 per record. In addition, in the FY 2017 IPPS/LTCH IPPS final rule (81 FR 57261), we finalized that for eCQM validation, we reimburse hospitals at $3.00 per record for providing medical records as electronic files submitted via secure file transmission (paper copies and digital portable media are not accepted for eCQM validation). Because we directly reimburse, we do not anticipate any net change in information collection burden associated with our finalized proposal to require electronic file submissions of medical records via secure file transmission for hospitals selected for chart-abstracted measures validation; hospitals would continue to be reimbursed at $3.00 per record.

We do not anticipate any net change in information collection burden associated with our finalized proposals to align the data submission quarters, to combine the hospital selection process by reducing the pool of hospitals randomly selected for validation for chart-abstracted measures from 400 hospitals to up to 200 hospitals, or to combine the scoring processes to provide one combined validation score for the validation of chart-abstracted measures and eCQMs. However, we refer readers to section I.K. of Appendix A of this final rule for a discussion of how our finalized proposals to align the validation processes for chart-abstracted measures and eCQMs may have the potential to reduce burden other than information collection burden. In addition, we do not anticipate any

information collection burden associated with our finalized proposal to formalize the process for conducting educational reviews for eCQM validation. As discussed in section VIII.A.11.b.(3). of the preamble to this final rule, this process would allow any validated hospital to request an educational review of their eCQM validation results with CMS.

We previously estimated the information collection burden associated with eCQM validation to be 80 minutes per record, or approximately 11 hours per hospital per year (80 minutes per record × 8 records × 1 quarter/60 = 10.67 hours) (81 FR 57261). We estimated a total annual burden of approximately 2,200 hours across 200 IPPS hospitals selected for eCQM validation each year (11 hours × 200 IPPS hospitals). Using the updated wage estimate as described previously, we estimate this to represent a total annual cost of $85,360 (2,200 hours × $38.80) across 200 hospitals.

The previous estimate of 80 minutes per record was based on our limited experience working with voluntary hospital participants during the eCQM validation pilot conducted in 2015 (79 FR 50269 through 50272). For the validation pilot, participating hospitals attended a 30-minute pre-briefing session and had to install CMS-approved software that allowed our Clinical Data Abstraction Center (CDAC) contractor to remotely view isolated records in real-time under hospital supervision in order to compare all abstracted data with QRDA Category I file data and summarize the results of the real-time session (79 FR 50270). Since this 2015 pilot, the eCQM validation process that we have implemented under the Hospital IQR Program has been significantly streamlined so that we no longer need hospitals to allow remote access to the CDAC contractor to view records in real-time under each hospital's supervision nor for them to engage in discussions with our contractor during the process. Instead, hospitals selected for eCQM validation are required to submit timely and complete copies of medical records on eCQMs selected for validation to CMS by submitting records in PDF file format within 30 calendar days following the medical records request date listed on the CDAC request form via the QualityNet secure file transmission process (81 FR 57179).

Based on this updated process, as well as hospitals having gained several years of experience using EHRs, we are revising our previous estimate from 80 minutes per record to 10 minutes per record. This is the amount of time we estimate is needed for hospitals to create PDF files and to electronically submit each medical record to us via the CMS-approved secure file transmission process. The estimate of 10 minutes per record is similar to our estimate of 10 minutes per eCQM per quarter in submitting QRDA Category I files via the QualityNet secure portal (81 FR 57260). We note that as mentioned previously, hospitals will still be reimbursed at $3.00 per record (81 FR 57261).

In addition, we anticipate that our finalized proposal to progressively increase the number of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, would similarly increase the total number of quarters of data from which cases would be selected for eCQM validation over a 3-year period. We also anticipate that our finalized proposal to combine the hospital selection process such that the Hospital IQR Program would validate a pool of up to 400 hospitals across measure types (up to 200 hospitals would be randomly selected and up to 200 hospitals would be selected using targeting criteria) would increase the number of hospitals selected for eCQM validation from up to 200 hospitals to up to 400 hospitals. Therefore, we estimate the following burden changes over a 3-year period using the revised estimate of 10 minutes (0.1667 hours) per record as discussed previously. For eCQM validation of CY 2021 data affecting the FY 2024 payment determination, we estimate a total burden of 1,067 hours across 400 IPPS hospitals selected for eCQM validation (0.1667 hours × 2 quarters × 8 cases × 400 IPPS hospitals) and $41,400 (1,067 hours × 38.80). This reflects a total burden decrease of 1,133 hours (2,200 hours − 1,067 hours) and $43,960 ($85,360 − $41,400) compared to our previous burden estimate for eCQM validation affecting the FY 2024 payment determination. For eCQM validation of CY 2022 data affecting the FY 2025 payment determination, we estimate a total burden of 1,600 hours across 400 IPPS hospitals selected for eCQM validation (0.1667 hours × 3 quarters × 8 cases × 400 IPPS hospitals) and $62,080 (1,600 hours × $38.80). This reflects a total burden decrease of 600 hours (2,200 hours − 1,600 hours) and $23,280 ($85,360 − $62,080) compared to our previous burden estimate for eCQM validation affecting the FY 2025 payment determination. For eCQM validation of CY 2023 data affecting the FY 2026 payment determination, and for subsequent years, we estimate a total burden of 2,133 hours across 400 IPPS hospitals selected for eCQM validation (0.1667 hours × 4 quarters × 8 cases × 400 IPPS hospitals) and $82,760 (2,133 hours × $38.80). This reflects a total burden decrease of 67 hours (2,200 hours − 2,133 hours) and $2,600 ($85,360 − $82,760) compared to our previous burden estimate for eCQM validation affecting the FY 2026 payment determination and subsequent years.

e. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate that the policies finalized in this final rule will result in an increase of 6,533 hours (6,660 − 67 hours) for 3,300 IPPS hospitals across a 4-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination. The total cost increase related to this information collection is approximately $253,480 (6,533 hours × $38.80) (which also reflects use of an updated hourly wage rate as previously discussed). The tables summarize the total burden changes for each respective FY payment determination compared to our currently approved information collection burden estimates (the table for the FY 2026 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022.

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Summary of Hospital IQR Program Information Collection Burden Change for the CY 2021 Reporting Period/FY 2023 Payment Determination

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2023 Payment Determination								
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 2 Quarters for 4 eCQMs	40	2	3,300	N/A	1.33	4,400	2,200	2,200
	Total Change in Information Collection Burden Hours: 2,200							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (2,200) = **$85,360**							

Summary of Hospital IQR Program Information Collection Burden Change for the CY 2022 Reporting Period/FY 2024 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2024 Payment Determination							
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 3 Quarters for 4 eCQMs	40	3	3,300	N/A	2	6,600	2,200	4,400
Increase Number of Hospitals Selected for eCQM Validation and Quarters of Data Validated from 1 to 2 Quarters	10*	2	400	8	2.67	1,067	2,200	-1,133
	Total Change in Information Collection Burden Hours: 3,267							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (3,267) = **$126,760**							

*Reflects revised estimate from 80 minutes per record to 10 minutes per record as discussed previously.

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Summary of Hospital IQR Program Information Collection Burden Change for the CY 2023 Reporting Period/FY 2025 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2025 Payment Determination							
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 4 Quarters for 4 eCQMs	40	4	3,300	N/A	2.67	8,800	2,200	6,600
Increase Number of Hospitals Selected for eCQM Validation and Quarters of Data Validated from 1 to 3 Quarters	10*	3	400	8	4	1,600	2,200	-600
	Total Change in Information Collection Burden Hours: 6,000							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (6,000) = **$232,800**							

*Reflects revised estimate from 80 minutes per record to 10 minutes per record as discussed previously.

Summary of Hospital IQR Program Information Collection Burden Change for the CY 2024 Reporting Period/FY 2026 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2026 Payment Determination							
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 4 Quarters for 4 eCQMs	40	4	3,300	N/A	2.67	8,800	2,200	6,600
Increase Number of Hospitals Selected for eCQM Validation and Quarters of Data Validated from 1 to 4 Quarters	10*	4	400	8	5.33	2,133	2,200	-67
	Total Change in Information Collection Burden Hours: 6,533							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (6,533) = **$253,480**							

*Reflects revised estimate from 80 minutes per record to 10 minutes per record as discussed previously.

A number of commenters expressed concern about an increase in burden related to our eCQM related proposals to increase the number of required reporting quarters for eCQM data and our proposal to begin publicly reporting eCQM data.

We believe the long-term benefits associated with reporting a full year of electronic data will outweigh the burdens and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers. We stated our intention in the FY 2018 IPPS/LTCH PPS final rule to gradually transition toward more robust eCQM reporting (82 FR 38356). We reiterated this stated goal to incrementally increase the use of EHR data for quality measurement in a subsequent final rule (84 FR 42502). We believe that taking an incremental approach to increasing eCQM reporting over a 3-year period will help to ease the burdens associated with reporting larger amounts of data and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting. For a detailed discussion of comments we received on the information collection burden associated with the finalization of these proposals, please see section VIII.A.10 of the preamble of this final rule. We believe the finalization of these proposals effectively balances the burdens associated with increased reporting of eCQM data and the benefits of providing that quality data to patients and consumers.

8. ICRs for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section VIII.B. of the preamble of this final rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

As discussed in section VIII.B.3. of the preamble of this final rule, we are finalizing our proposal to adopt refined versions of two existing measures: Catheter-associated Urinary Tract Infection (CAUTI) and Central Line-associated Bloodstream Infection (CLABSI), beginning with the FY 2023 program year. The refined versions of the measure incorporate an updated SIR calculation methodology developed by the Centers for Disease Control and Prevention (CDC) that calculates rates stratified by patient care locations within PCHs, without the use of predictive models or comparisons in the rate calculations. We do not estimate any net change in burden hours for the PCHQR Program for the FY 2023 program year because there would be no change in the data submission requirements for PCHs. We note that burden estimates for these CDC NHSN measures are submitted separately under OMB control number 0920–0666.

The PCHQR Program measure set would continue to consist of 15 measures for the FY 2023 program year. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $19.40 (previously $18.83).[527] Consequently, while our finalized policy will not yield a net change in burden hours, the change in labor wage will cause an increase in burden cost for the PCHQR Program. Therefore, using the previously finalized [528] hourly burden estimate of 75,779 burden hours across the 11 PCHs for data collection and submission of all 15 measures, we estimate a total annual labor cost of $2,940,225 (75,779 hours × $38.80 per hour) for all 11 PCHs for the FY 2023 program year. The burden hours associated with these reporting requirements is currently approved under OMB control number 0938–1175. The updated burden cost, based on the increase in the labor wage, will be submitted to OMB.

We received no comments in response to the burden estimates specifically discussed above. Thus, we are finalizing them without modification.

9. ICRs for the Promoting Interoperability Programs

In section VIII.D. of the preamble of this final rule, we discuss several finalized proposals for the Medicare and Medicaid Promoting Interoperability Programs. OMB has currently approved 623,562 total burden hours and approximately $61 million under OMB control number 0938–1278, accounting for information collection burden experienced by approximately 3,300 eligible hospitals and CAHs (serving Medicare-only and dual eligible beneficiaries) that attest to CMS under the Medicare Promoting Interoperability Program. The collection of information burden analysis in this final rule focuses on eligible hospitals and CAHs that attest to the objectives and measures, and report CQMs, under the Medicare Promoting Interoperability Program for the reporting period in CY 2021.

b. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program

In section VIII.D.3.b. of the preamble of this final rule, we are finalizing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; (3) to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; (4) to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a 3-year period. Specifically, we propose to require: (a) 2 self-selected calendar quarters of data for the CY 2021 reporting period; (b) 3 self-selected calendar quarters of data for the CY 2022 reporting period; and (c) 4 calendar quarters of data beginning with the CY 2023 reporting period, where the submission period for the Medicare Promoting Interoperability Program will be the 2 months following the close of the respective calendar year; (5) to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021 on the *Hospital Compare* and/or *data.medicare.gov* websites or successor websites; (6) to correct errors and amend regulation text under § 495.104(c)(5)(viii)(B) through (D) regarding transition factors under section 1886(n)(2)(E)(i) of the Act for the incentive payments for Puerto Rico eligible hospitals; and (7) to correct errors and amend regulation text under § 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) for regulatory citations for the ONC certification criteria. We are finalizing the amendments to the regulations to incorporate the proposed changes.

[527] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[528] FY 2020 IPPS/LTCH PPS Final Rule PRA Revision Submission. OMB Control Number 0938–1175: ''*Supporting Statement-A*'' Accessed on 1/8/2020. Available at: *https://protect2.fireeye.com/url?k=f221f793-ae75deb8-f221c6ac-0cc47a6d17cc-43510bdd6105db67&u= https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201910-0938-003.*

c. Summary of Collection of Information Burden Estimates

(1) Summary of Estimates Used To Calculate the Collection of Information Burden

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated it will take an individual provider or designee approximately 10 minutes to attest to each objective and associated measure that requires a numerator and denominator to be generated. The measures that require a ''yes/no'' response will take approximately one minute to complete. We estimated that the Security Risk Analysis measure will take approximately 6 hours for an individual provider or designee to complete (we note this measure is still part of the program, but is not subject to performance-based scoring). We continue to believe these are appropriate burden estimates for reporting and have used this methodology in our collection of information burden estimates for this final rule.

Given the proposals, we estimated a total burden estimate of 6 hours 31 minutes per respondent (6.5 hours) which remains unchanged from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044).

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden Per Respondent for CY 2021: § 495.24(e) - Objectives/Measures Medicare (Eligible Hospitals/CAHs)

Objective	Measure	Burden Estimate per Eligible Hospital and CAH
N/A	Security Risk Analysis	6 hours
Electronic Prescribing	e-Prescribing	10 minutes
	Query of PDMP	
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	10 minutes
	Support Electronic Referral Loops by Receiving and Incorporating Health	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	10 minutes
Public Health and Clinical Data Exchange	• Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry -Reporting • Electronic Reportable Laboratory Result Reporting	1 minute
Total Burden Estimate per Respondent		6 hours 31 minutes (6.5 hours)

(2) Hourly Labor Costs

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated a mean hourly rate of $63.46 for the staff involved in attesting to EHR technology, meaningful use objectives and associated measures, and electronically submitting the clinical quality measures. We had previously used the mean hourly rate of $68.22 for the necessary staff involved in attesting to the objectives and measures under 42 CFR 495.24(e) in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42609), however, this rate has since been updated to $69.34 for the FY 2021 final rule based upon recently-released 2018 data from the Bureau of Labor Statistics (BLS).[529]

We are finalizing these provisions as proposed, therefore, we do not estimate any net change in burden hours for the Medicare Promoting Interoperability Program for CY 2021, as there is no substantive change in measures or data submission requirements for eligible hospitals and CAHs in our proposals. However, we discovered an incorrect mathematical calculation in last year's final rule and are correcting it in the table that follows. The correction we are providing in following table is that 3,300 responses multiplied by 6.5 burden hours equals 21,450 total annual burden hours (a decrease in 44 hours from what was mistakenly reported last year). While we reiterate that the provisions included in this rule do not contribute to additional or reduced burden hours, please note that the correction of this error will update subsequent burden calculations detailed later in this section.

As previously stated, recent data from the BLS reflects a median hourly staff wage of $69.34 (previously $68.22). Consequently, while our proposal will not yield a net change in burden hours, the change in labor wage will cause an increase in burden cost for the program. Therefore, using the updated estimate of total annual burden hours of 21,450 burden hours across 3,300 responses to data collection and submissions for the program objectives' measures, we estimate a total annual labor cost of $1,487,343 (21,450 hours × $69.34 per hour) for the CY 2021 EHR reporting period. The burden hours associated with these reporting requirements is currently approved under OMB control number 0938–1278. The updated burden cost, based solely on the increase in labor wages, will be revised and submitted to OMB.

[529] *https://www.bls.gov/oes/current/oes231011.htm.*

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden (Total Cost) for CY 2021

Regulations Section	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
§495.24(e)	3,300	3,300	6.5	21,450	69.34	1,487,343

As no measures have been removed nor introduced since last year's final rule, but are mainly continuations of current policies, we do not consider the finalized proposals included in this section to change the program. That being said, the numerical-correction of the total annual burden hours and an updated BLS hourly labor cost of reporting will impact the program's total cost. Thus, the Collection Burden's Total Cost for CY 2021 of $1,487,343 is an increase of $24,024 from last year's final rule.

We did not receive comments on to the information collection requirement discussed in this section.

10. ICR for the Submission of Electronic Medical Records to Quality Improvement Organizations (QIOs)

In section IX.A. of this final rule, we discuss the changes we are finalizing relating to the submission of patient records to the QIOs in an electronic format by providers and practitioners in accordance with § 476.78 and by institutions and practitioners in accordance with § 480.111. These patient records must be submitted to the QIOs for purposes of one or more QIO functions. As a result, the collection and review of such records by the QIOs constitutes an audit, investigation or administrative action as specified in section 1154(a) of the Act. Therefore, we believe these collection requirements are not subject to the PRA as stipulated under 5 CFR 1320.4(a)(2).

11. ICR for Payer-Specific Negotiated Charges Data Collection

Section IV.P. of the preamble of this final rule discusses the collection of market-based payment rate information by MS–DRG on the Medicare cost report for cost reporting periods ending on or after January 1, 2021. Hospitals would report the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations. We proposed to collect this market-based information on new form CMS–2552–10, Worksheet S–12. The required cost report reporting changes to accomplish this will be in more detail in the Information Collection Request approved under OMB No. 0938–0050, which is subject to a separate comment solicitation.

We believe reporting this market based information will be less burdensome for hospitals given that hospitals are required, beginning in CY 2021, to make public their payer-specific negotiated charges for the same service packages under the requirements we finalized in the Hospital Price Transparency final rule. The market-based rate information we are finalizing to collect on the Medicare cost report would be the median of the payer-specific negotiated charges for every MS–DRG, that the hospital has negotiated with its MA organizations. We believe that because hospitals are already required to publically report the payer-specific negotiated charge information that they will use to calculate these medians, the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

Burden hours estimate the time (number of hours) required for each IPPS hospital to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the Form CMS–2552–10, Worksheet S–12. The most recent data from the System for Tracking Audit and Reimbursement, an internal CMS data system maintained by the Office of Financial Management (OFM), reports that 3,189 hospitals, the current number of Medicare certified IPPS hospitals, file Form CMS–2552–10 annually.

In section IV.P.2.c. of the preamble to this final rule, we finalized that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information, as proposed. Hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this definition. Hospitals that are exempted from this policy include, Critical Access Hospitals (CAHs), hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model, during the performance period of that Model, hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act, and federally owned and operated facilities, and non-subsection (d) hospitals. Based on this policy, we estimate that 3,189 hospitals would be required to comply with this market-based data collection requirement.

Based on our understanding of the resources necessary to report this information, we estimate an average annual burden per hospital of 20 hours (5 hours for recordkeeping and 15 hours for reporting) for the Worksheet S–12. This represents an increase of 5 hours over the burden estimate provided within the proposed rule, based on feedback from commenters that additional effort would be necessary to crosswalk inpatient discharges to an MS–DRG, specifically if a hospital is not familiar with the MS–DRG classification system, for use in calculating the median payer-specific negotiated charges. The burden is minimized because the median payer-specific negotiated charge data collected on the Worksheet S–12 is based on payer-specific data already maintained by the hospital. We believe that since hospitals assign the underlying ICD–10–CM principal diagnosis, and any other secondary diagnosis codes and ICD–10–PCS procedure codes, which determine how patients are assigned to an MS–DRG, that hospitals are able to associate those items and services to MS–DRGs for each discharge. Additionally, hospitals that are not as familiar with MS–DRGs have access to the most current publically available version of the CMS Grouper used to group ICD–10 codes to MS–DRGs, and are able to use this software to uniformly group inpatient items and services to MS–DRGs, either initially by proactively using the same Grouper version used by CMS, or retrospectively after an inpatient hospital stay, but prior to submitting this information on the hospital cost report.

We estimated the total annual burden hours as follows: 3,189 hospitals times 20 hours per hospital equals 63,780 annual burden hours.

The 5 hours for recordkeeping include hours for bookkeeping, accounting and auditing clerks; the 15 hours for reporting include accounting and audit professionals' activities. We believe the basic median calculation would be captured within the recordkeeping portion of this assessment.

Based on the most recent Bureau of Labor Statistics (BLS) in its 2019 Occupation Outlook Handbook, the mean hourly wage for Category 43–3031 (bookkeeping, accounting and auditing clerks) is $20.65 (*https://www.bls.gov/oes/current/oes433031.htm*). We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $41.30 ($20.65 + $20.65) and multiplied it by 5 hours, to determine the annual recordkeeping costs per hospital to be $206.50 ($41.30 × 5 hours).

The mean hourly wage for Category 13–2011 (accounting and audit professionals) is $38.23 (*www.bls.gov/oes/current/oes132011.htm*). We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $76.46 ($38.23 + $38.23) and multiplied it by 15 hours, to determine the annual reporting costs per hospital to be $1,146.90 ($76.46 × 15 hours). We have calculated the total annual cost per hospital of $1,353.40 by adding the recordkeeping costs of $206.50 plus the reporting costs of $1,146.90 (see Table K1). We estimated the total annual cost to be $4,315,993 ($1,353.40 × 3,189 IPPS hospitals) (see Table K2).

Table K1: Estimated Annual Cost per Hospital

Average Hourly Rate Analysis: August 2020	Hours Per Response	BLS Cost Per Hour	Cost Per Hour with Overhead and Fringes	Cost Per Response	Average Hourly Rate
Reporting	15	38.23	76.46	1146.90	
Record Keeping	5	20.65	41.30	206.50	
Third Party Disclosure					
Total	20			1353.40	N/A

Table K2: Estimated Total Annual Cost

	Currently Approved			Total Requested			Increase/(Decrease) Over Currently Approved	
Respondent Costs	Number of Providers	Per Provider	Total Hours	Number of Providers	Per Provider	Total Hours	Number of Providers	Total
Hours required for CR preparation	3,189	-	-	3,189	20	63,780	-	63,780
Cost for CR preparation						$4,315,993		$4,315,993

We believe that because hospitals are already required to publically report the payer-specific negotiated charge information that they will use to calculate these medians, the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals than if hospitals did not already have this information compiled. The Hospital Price Transparency final rule required that hospitals establish, update, and make public via the internet standard charges in two different ways: (1) A single machine-readable file with a list of standard charges (including gross charges, payer-specific negotiated charges, de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices) for all items and services including service packages identified by MS–DRG; and (2) standard charges (including payer-specific negotiated charges, discounted cash prices, de-identified minimum negotiated charges, de-identified maximum negotiated charges) in a consumer-friendly manner for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services. We note that the data collection requirement in this final rule would apply to a smaller subset of hospitals as compared to the public reporting requirements under the Hospital Price Transparency final rule.

In total, the Hospital Price Transparency final rule estimated in the first year of public reporting, it would take a hospital an estimated 150 hours at a cost of $11,898.60 per hospital [530] to implement and comply with the requirements, as specified at 45 CFR part 180. The estimated 150 hours of burden for the first year includes 10 total hours for a lawyer ($138.68/hour) and general operations manager ($119.12/hour) to read and review the rule; 80 hours for a business operations specialist ($74.00/hour) to gather and compile the required information and post it in the form and manner specified in the Hospital Price Transparency final rule; 30 hours for a network and computer system administrator ($83.72/hour) to comply with the form and manner standards set forth in the

[530] The estimated hourly cost for each labor category used in this analysis were referencing the Bureau of Labor Statistics report on Occupational Employment and Wages, May 2018 (Bureau of Labor Statistics report on Occupational Employment and Wages, May 2018 Available at: *https://www.bls.gov/oes/2018/may/oes_nat.htm*). We also have calculated the cost of overhead at 100 percent of the mean hourly wage, in line with the Hospital Inpatient and Hospital Outpatient Quality Reporting programs (81 FR 57260 and 82 FR 59477, respectively).

Hospital Price Transparency final rule; 30 hours for a registered nurse ($72.60/hour) to capture the necessary clinical input to comply with reporting the CMS-specified and hospital-selected shoppable services. (150 hours = 5 hours + 5 hours + 80 hours + 30 hours + 30 hours; totaling a cost of $11,898.60 ($693.40 + $595.60 + $5,920 + $2,511.60 + $2,178) per hospital.)

In this final rule, we finalized the requirement for hospitals to calculate and report on the Medicare cost report the median payer-specific negotiated charge by MS–DRG using the payer-specific negotiated charge data that hospitals are required to make public under the Hospital Price Transparency final rule. Therefore, the burden associated with establishing and updating the payer-specific negotiated charges has already been assumed. Specifically, given that the payer-specific negotiated charge is one of the five types of standard charges (gross charges, payer-specific negotiated charges, de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices) that the Hospital Price Transparency final rule requires that hospitals estimate, update and make public, we believe that a fraction of the estimated 80 hours of burden associated with gathering, compiling, and posting, that required information in the form and manner specified in the Hospital Price Transparency final rule, would support the reporting efforts in this final rule. We heard from commenters that additional effort would be necessary to crosswalk discharges to an MS–DRG, specifically if a hospital is not familiar with the MS–DRG classification system, for use in calculating the median payer-specific negotiated charges. In recognition of this additional effort, we have increased the burden hours associated with reporting the median payer-specific negotiated charge. However, we note that much of the burden associated with gathering and compiling the payer-specific negotiated charge is captured initially in the Hospital Price Transparency burden estimate provided in that final rule. We refer readers to the Hospital Price Transparency final rule for the full burden assessment analysis for the requirements set forth within that final rule (84 FR 65524).

We maintain that the estimated burden associated with completing the Worksheet S–12 would be 20 hours (5 hours for recordkeeping and 15 hours for reporting), given the minimized burden since hospitals would already have collected the payer-specific negotiated charge data and would only then need to calculate the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations.

Further instructions for the reporting and complying with this market-based data collection requirement on the Medicare cost report will be discussed in a forthcoming revision of the ICR request currently approved under OMB control number 0938–0050, expiration date March 31, 2022.

12. Summary of All Burden in This Final Rule

The following chart reflects the total burden and associated costs for the provisions included in this final rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Inpatient Quality Reporting Program	+6,533	+$253,480
Hospital Value-Based Purchasing Program[1]	N/A	N/A
Hospital-Acquired Condition Reduction Program	-14,400	-$558,720
Hospital Readmissions Reduction Program[2]	N/A	N/A
Promoting Interoperability Programs	-44	+$24,024
PPS-Exempt Cancer Hospital Quality Reporting Program[3]	N/A	+$86,388
Payer-Specific Negotiated Charges Data Collection	+63,780	+$4,315,993
TOTAL	**+55,869**	**+$4,121,165**

* Numbers rounded.

[1] Because the FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this final rule.

[2] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for service- claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[3] The increase in cost is a function of the Bureau of Labor Statistics' updated labor wage.

C. Waiver of the 60-Day Delay in Effective Date for the Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the IPPS and LTCH PPS as required by law and we have worked diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accord with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, section 808(2) of the CRA provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines. In addition, the Administrative Procedure Act, (5 U.S.C. 553(d)), ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(ii) of the Act, also permits a substantive rule to take effect less than 30 days after its publication if the Secretary finds that waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in

all 50 States and the District of Columbia. The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020, the President of the United States declared the COVID–19 outbreak a national emergency.

The COVID–19 PHE has required the agency to divert energy and personnel resources that would otherwise have been used to complete this IPPS and LTCH PPS payment rule to other priority matters, including three interim final rules necessary because of the PHE. (See 85 FR 19230 (April 6, 2020); 85 FR 27550 (May 8, 2020); and the interim final rule scheduled to appear in the September 2, 2020 **Federal Register**.) Although we have devoted significant resources to completing the IPPS and LTCH PPS payment rule, it was impracticable for CMS to complete the work needed on the rule in accordance with our usual schedule for this rulemaking or in sufficient time to ensure a full 60-day period of public notice prior to the next fiscal year that begins on October 1, 2020. The IPPS and LTCH PPS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the fiscal year to which they are intended to apply. Therefore, in light of the COVID–19 PHE, and the resulting strain on CMS's resources, it was impracticable for CMS to publish this final rule either 30 or 60 days prior to the beginning of the upcoming fiscal year, and CMS has determined that, for good cause, it would be contrary to the public interest to delay the effective date of this final rule for any longer than 28 days.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Grant programs—health, Health care, Health facilities, Health professions, Quality Improvement Organizations (QIOs), Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Penalties, Privacy, Quality Improvement Organizations (QIOs), Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.1801 is amended—
■ a. In paragraph (a), in the definition of ''Date of receipt''—
■ i. By revising paragraphs (1)(ii) and (2) introductory text;
■ ii. In paragraph (2)(i) by removing ''; or'' and adding a period in its place; and
■ iii. By adding paragraph (2)(iii); and
■ b. By revising paragraph (d) introductory text.

The revisions and addition read as follows:

§ 405.1801 Introduction.

(a) * * *

Date of receipt * * *

(1) * * *

(ii) For purposes of a contractor hearing, if no contractor hearing officer is appointed (or none is currently presiding), the date of receipt of materials sent to the contractor hearing officer (as permitted under paragraph (d) of this section) is presumed to be, as applicable, the date that the contractor stamps ''Received'' on the materials, or the date of electronic delivery.

* * * * *

(2) *A reviewing entity.* For purposes of this definition, a reviewing entity is deemed to include the Office of the Attorney Advisor. The determination as to the date of receipt by the reviewing entity to which the document or other material was submitted (as permitted under paragraph (d) of this section) is final and binding as to all parties to the appeal. The date of receipt of documents by a reviewing entity is presumed to be, as applicable, one of the following dates:

* * * * *

(iii) Of electronic delivery. *In writing* or *written* means a hard copy or electronic submission (subject to the restrictions in paragraph (d) of this section), as applicable throughout this subpart.

* * * * *

(d) *Method for submissions and calculating time periods and deadlines.* Except for subpoena requests being sent to a nonparty under § 405.1857(c), the reviewing entity may prescribe the method(s) by which a party must make a submission, including the requirement to use an electronic filing system for submission of documents. Such methods or instructions apply to any period of time or deadline prescribed or allowed under this subpart (for example, requests for appeal under §§ 405.1811(b), 405.1835(b), and 405.1837(c) and (e)) or authorized by a reviewing entity. In computing any period of time or deadline prescribed or allowed under this subpart or authorized by a reviewing entity the following principles are applicable:

* * * * *

§ 405.1811 [Amended]

■ 3. Section 405.1811 is amended in paragraph (c)(1) by removing the phrase

''the date the contractor stamped'' and adding in its place is the phrase ''the date of electronic delivery, or the date the contractor stamped''.

§ 405.1813 [Amended]

■ 4. Section 405.1813 is amended—
■ a. In paragraph (d) by removing the phrase ''must give prompt written notice to the provider, and mail a copy'' and adding in its place is the phrase ''must send prompt written notice to the provider, and send a copy''; and
■ b. In paragraph (e)(1) by removing the phrase ''promptly mails the decision'' and adding in its place is the phrase ''promptly sends the decision''.

§ 405.1814 [Amended]

■ 5. Section 405.1814 is amended in paragraph (c)(2) by removing the phrase ''must be mailed promptly'' and adding in its place is the phrase ''must be sent promptly''.

§ 405.1819 [Amended]

■ 6. Section 405.1819 is amended by removing the phrase ''prior to the mailing of notice'' and adding in its place is the phrase ''prior to the sending of notice''.

§ 405.1821 [Amended]

■ 7. Section 405.1821 is amended—
■ a. In paragraph (c)(1) by removing the phrase ''be mailed promptly'' and adding in its place is the phrase ''be sent promptly''; and
■ b. In paragraph (c)(3)(iii)(B) by removing the phrase ''Issue and mail'' and adding in its place is the phrase ''Issue and send''.

§ 405.1831 [Amended]

■ 8. Section 405.1831 is amended in paragraph (d) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1834 [Amended]

■ 9. Section 405.1834 is amended in paragraph (e)(3) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1835 [Amended]

■ 10. Section 405.1835 is amended—
■ a. In paragraph (b) introductory text by removing ''in writing to the Board'', ''(b)(1) through (b)(4)'', and ''(b)(1), (b)(2), or (b)(3)'' and adding in their places ''in writing in the manner prescribed by the Board'', ''(b)(1) through (4)'', and ''(b)(1), (2), or (3)'', respectively.
■ b. In paragraph (d) introductory text by removing ''in writing to the Board'', ''(d)(1) through (d)(4)'', and ''(d)(1), (d)(2), or (d)(3)'' and adding in their places ''in writing in the manner prescribed by the Board'', ''(d)(1) through (4)'', and ''(d)(1), (2), or (3)'', respectively.

§ 405.1836 [Amended]

■ 11. Section 405.1836 is amended—
■ a. In paragraph (d) by removing the phrase ''and mail a copy'' and adding in its place is the phrase ''and send a copy''; and
■ b. In paragraph (e)(1) by removing the phrase ''of this subpart'' in two places and removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1840 [Amended]

■ 12. Section 405.1840 is amended paragraph (c)(2) by removing the phrase ''of this subpart'' in two places and removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

■ 13. Section 405.1843 is amended—
■ a. By redesignating paragraph (a) as paragraph (a)(1);
■ b. In newly redesignated paragraph (a)(1) by removing the phrase ''of this subpart'';
■ c. By adding paragraph (a)(2); and
■ d. In paragraph (d)(2) by removing the phrase ''promptly mail copies'' and adding in its place is the phrase ''promptly send copies''.

The addition reads as follows:

§ 405.1843 Parties to proceedings in a Board appeal.

(a) * * *

(2) All parties to a Board appeal are to familiarize themselves with the instructions for handling a Provider Reimbursement Review Board (PRRB) appeal, including any and all requirements related to the electronic/online filing of documents.

* * * * *

§ 405.1845 [Amended]

■ 14. Section 405.1845 is amended in paragraph (h)(2)(iii) by removing the phrase ''Mail the remand'' and adding in its place is the phrase ''Send the remand''.

§ 405.1849 [Amended]

■ 15. Section 405.1849 is amended by removing the phrase ''mail written notice thereof to the parties at their last known addresses,'' and adding in its place is the phrase ''send notice thereof to the parties' contact information on file,''.

§ 405.1851 [Amended]

■ 16. Section 405.1851 is amended by removing the phrase ''mailing of notice'' and adding in its place is the phrase ''issuing of the notice''.

§ 405.1853 [Amended]

■ 17. Section 405.1853 is amended in paragraph (e)(5)(vi)(A) by removing the phrase ''issue and mail'' and adding in its place is the phrase ''issue and send''.

■ 18. Section 405.1857 is amended—
■ a. By revising paragraph (c)(1) introductory text; and
■ b. In paragraph (c)(4)(iii)(A) by removing the phrase ''mail promptly to each party'' and adding in its place is the phrase ''send promptly to each party''.

The revision reads as follows:

§ 405.1857 Subpoenas.

* * * * *

(c) * * *

(1) *Subpoena requests.* The requesting party must send any subpoena request submitted to the Board promptly to the party or nonparty subject to the subpoena, and to any other party to the Board appeal. If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena request must be sent by certified mail. The request must—

* * * * *

§ 405.1868 [Amended]

■ 19. Section 405.1868 is amended in paragraph (d)(1) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1871 [Amended]

■ 20. Section 405.1871 is amended in paragraph (a)(5) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1875 [Amended]

■ 21. Section 405.1875 is amended—
■ a. In paragraph (c)(1)(iv) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''; and
■ b. In paragraph (e)(2) by removing the phrase ''mail a copy'' and adding in its place is the phrase ''send a copy''.

§ 405.1885 [Amended]

■ 22. Section 405.1885 is amended—
■ a. In paragraph (b)(1) by removing the phrase ''of this subpart'' and by removing the term ''mailed'' and adding in its place the term ''sent'' each time it appears; and
■ b. In paragraph (b)(2)(i) by removing the phrase ''request to reopen is conclusively presumed to be the date of delivery by a nationally-recognized next-day courier, or the date stamped ''Received'' by CMS, the contractor or

the reviewing entity (where a nationally-recognized next-day courier is not employed),'' and adding in its place the phrase ''request to reopen is determined by applying the date of receipt presumption criteria for reviewing entities defined in § 405.1801(a),''.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 23. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 24. Section 412.1 is amended by revising paragraph (a)(1) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) This part implements sections 1886(d) and (g) of the Act by establishing a prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983, and a prospective payment system for the capital-related costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1991.

(i) Under these prospective payment systems, payment for the operating and capital-related costs of inpatient hospital services furnished by hospitals subject to the systems (generally, short-term, acute-care hospitals) is made on the basis of prospectively determined rates and applied on a per discharge basis.

(ii) Payment for other costs related to inpatient hospital services (organ acquisition costs incurred by hospitals with approved organ transplantation centers, the costs of qualified nonphysician anesthetist's services, as described in § 412.113(c), direct costs of approved nursing and allied health educational programs, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant as described in § 412.113(e)) is made on a reasonable cost basis.

(iii) Payment for the direct costs of graduate medical education is made on a per resident amount basis in accordance with §§ 413.75 through 413.83 of this chapter.

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, and for serving a disproportionate share of low-income patients.

(v) Under either prospective payment system, a hospital may keep the difference between its prospective payment rate and its operating or capital-related costs incurred in furnishing inpatient services, and the hospital is at risk for inpatient operating or inpatient capital-related costs that exceed its payment rate.

* * * * *

■ 25. Section 412.2 is amended by adding paragraph (e)(6) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(e) * * *

(6) For cost reporting periods beginning on or after October 1, 2020, the costs of allogenic hematopoietic stem cell acquisition, as described in § 412.113(e), for the purpose of an allogeneic hematopoietic stem cell transplant.

* * * * *

■ 26. Section 412.64 is amended by adding paragraph (e)(5) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(e) * * *

(5) CMS makes an adjustment to the standardized amount to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are made in a manner so that aggregate payments to hospitals are not affected.

* * * * *

§ 412.82 [Amended]

■ 27. Section 412.82 is amended in paragraph (c) by removing the reference ''§ 412.86'' and adding in its place ''§ 412.83''.

■ 28. Section 412.85 and an undesignated center heading preceding the section are added to read as follows:

Payment Adjustment for Certain Clinical Trial Cases and Expanded Access Use Immunotherapy

§ 412.85 Payment adjustment for certain clinical trial and expanded access use immunotherapy cases.

(a) *General rule.* For discharges occurring on or after October 1, 2020, the amount of payment for a discharge described in paragraph (b) of this section is adjusted as described in paragraph (c) of this section.

(b) *Discharges subject to payment adjustment.* Payment is adjusted in accordance with paragraph (c) of this section for discharges assigned to MS–DRG 018 involving expanded access use of immunotherapy, or that are part of an applicable clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge.

(c) *Adjustment.* The DRG weighting factor determined under § 412.60(b) is adjusted by a factor that reflects the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy, or are part of an applicable clinical trial, to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of an applicable clinical trial.

§ 412.86 [Redesignated as § 412.83]

■ 29. Section 412.86 is redesignated as § 412.83.

§ 412.86 [Added and Reserved]

■ 30. New reserved § 412.86 is added.

■ 31. Section 412.87 is amended by revising paragraphs (c)(1), (d) introductory text, (d)(1), the paragraph (e) subject heading, and (e)(2) and by adding paragraph (e)(3) to read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(c) * * *

(1) A new medical device is part of the Food and Drug Administration's (FDA) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

* * * * *

(d) *Eligibility criteria for alternative pathway for certain antimicrobial products.* (1)(i) A new medical product is designated by FDA as a Qualified Infectious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation; or

(ii) For discharges occurring on or after October 1, 2021, a new medical product is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway.

* * * * *

(e) *Announcement of determinations and deadline for consideration of new medical service or technology applications, and conditional approval for certain antimicrobial products.*

* * *

(2) Except as provided for in paragraph (e)(3) of this section, CMS

only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by July 1 prior to the particular fiscal year.

(3) A technology for which an application is submitted under an alternative pathway for certain antimicrobial products under paragraph (d) of this section that does not receive FDA marketing authorization by the July 1 deadline specified in paragraph (e)(2) of this section may be conditionally approved for the new technology add-on payment for a particular fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

■ 32. Section 412.88 is amended—

■ a. In paragraph (a)(2)(ii)(A) introductory text by removing the reference ''paragraph (a)(2)(ii)(*2*) of this section'' and adding in its place ''paragraph (a)(2)(ii)(B) of this section'';

■ b. By revising paragraphs (a)(2)(ii)(B) introductory text and (b)(2).

The revisions read as follows:

§ 412.88 Additional payment for new medical service or technology.

(a) * * *

(2) * * *

(ii) * * *

(B) For a medical product designated by FDA as a Qualified Infectious Disease Product or, for discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

* * * * *

(b) * * *

(2) *For discharges occurring on or after October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus—

(i) 65 percent of the estimated costs of the new medical service or technology;

(ii) For a medical product designated by FDA as a Qualified Infectious Disease Product, 75 percent of the estimated costs of the new medical service or technology; or

(iii) For discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, 75 percent of the estimated costs of the new medical service or technology.

■ 32. Section 412.92 is amended by revising paragraph (c)(3) to read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(c)* * *

(3) The term *service area* means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital. If the most recent cost reporting period ending before the hospital applies for classification as a sole community hospital is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

* * * * *

■ 33. Section 412.96 is amended by adding paragraph (c)(2)(iii) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(c) * * *

(2) * * *

(iii) If the hospital's cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section is for less than 12 months or longer than 12 months, the hospital's number of discharges for that cost reporting period will be annualized to estimate the total number of discharges for a 12-month cost reporting period.

* * * * *

■ 34. Section 412.104 is amended by revising paragraph (a) to read as follows:

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* CMS provides an additional payment to a hospital for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into any of the following MS–DRGs, where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges:

(1) MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis).

(2) MS–DRGs 650 and 651 (Kidney Transplant with Hemodialysis with MCC, without MCC, respectively).

(3) MS–DRGs 682, 683, and 684 (Renal Failure with MCC, with CC, without CC/MCC, respectively).

* * * * *

§ 412.105 [Amended]

■ 35. Section 412.105 is amended in paragraph (f)(1)(ix)(A)—

■ a. By removing the phrase ''to reflect residents added because'' and adding in its place the phrase ''to reflect displaced residents added because'' each time it appears.

■ b. By removing the citations ''§§ 413.79(h)(1) and (h)(2)'', ''§§ 413.79(h)(1) and (h)(3)(ii)'', and ''§§ 413.79(h)(1) and (h)(3)(i)'' and adding in their places the citations ''§ 413.79(h)(1) and (2)'', ''§ 413.79(h)(1) and (h)(3)(ii)'', and ''§ 413.79(h)(1) and (h)(3)(i)'', respectively.

■ 36. Section 412.106 is amended by removing the semicolon at the end of paragraph (g)(1)(iii)(C)(*6*) and adding a period in its place and adding paragraphs (g)(1)(iii)(C)(*7*) and (*8*).

The additions read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*7*) For fiscal year 2021, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from 2017 cost reports from the most recent Hospital Cost Report Information System (HCRIS) database extract, except that, for Puerto Rico hospitals and Indian Health Service or Tribal hospitals, CMS will base its estimates on utilization data for Medicaid and Medicare Supplemental Security Income (SSI) patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*8*) For each subsequent fiscal year, for all eligible hospitals, except Indian Health Service and Tribal hospitals and Puerto Rico hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on

uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the most recent cost reporting year for which audits have been conducted.

* * * * *

■ 37. Section 412.113 is amended by adding paragraph (e) to read as follows:

§ 412.113 Other payments.

* * * * *

(e) *Allogeneic hematopoietic stem cell acquisition.* For cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, payment to such hospital for hematopoietic stem cell acquisition costs is made on a reasonable cost basis.

(1) An allogeneic hematopoietic stem cell transplant is the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.

(2) Allogeneic hematopoietic stem cell acquisition costs recognized under this paragraph (e) are costs of acquiring hematopoietic stem cells from a donor. These costs are as follows:

(i) Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor.

(ii) Tissue typing of donor and recipient.

(iii) Donor evaluation.

(iv) Physician pre-admission/pre-procedure donor evaluation services.

(v) Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services), and transportation costs of stem cells if the recipient hospital incurred or paid such costs.

(vi) Post-operative/post-procedure evaluation of donor.

(vii) Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

(3) A subsection (d) hospital that furnishes inpatient allogeneic hematopoietic stem cell transplants is required to hold all allogeneic hematopoietic stem cell acquisition charges and bill them to Medicare using the appropriate revenue code, when the transplant occurs.

(4) A subsection (d) hospital must maintain an itemized statement that identifies, for all costs defined in paragraph (e)(2) of this section, the services furnished in collecting hematopoietic stem cells including all invoices or statements for purchased services for all donors and their service charges. Records must be for the person receiving the services (donor or recipient; for all donor sources, the hospital must identify the prospective recipient), and the recipient's Medicare beneficiary identification number.

■ 38. Section 412.115 is amended by revising paragraph (c) to read as follows:

§ 412.115 Additional payments.

* * * * *

(c) *QIO reimbursement for cost of sending requested patient records to the QIO.* An additional payment is made to a hospital in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

■ 39. Section 412.152 is amended by revising the definitions of ''Applicable period'' and ''Applicable period for dual eligibility'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

(1) The applicable period for FY 2022 is the 3-year period from July 1, 2017 through June 30, 2020; and

(2) Beginning with the FY 2023 program year, the applicable period is the 3-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary.

Applicable period for dual eligibility is the 3-year data period corresponding to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise established by the Secretary.

* * * * *

■ 40. Section 412.170 is amended by revising the definition of ''Applicable period'' and adding definitions for ''CDC NHSN HAI'' and ''CMS PSI 90'' in alphabetical order to read as follows:

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

* * * * *

Applicable period is, unless otherwise specified by the Secretary, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

(1) The applicable period for FY 2022—

(i) For the CMS PSI 90 measure, is the 24-month period from July 1, 2018 through June 30, 2020; and

(ii) For the CDC NHSN HAI measures, is the 24-month period from January 1, 2019 through December 31, 2020.

(2) Beginning with the FY 2023 program year, the applicable period is the 24-month period advanced by 1-year from the prior fiscal year's period from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program, unless otherwise specified by the Secretary.

CDC NHSN HAI stands for Centers for Disease Control and Prevention National Healthcare Safety Network healthcare-associated infection measures.

CMS PSI 90 stands for Patient Safety and Adverse Events Composite for Selected Indicators (modified version of PSI 90).

* * * * *

■ 41. Section 412.230 is amended by revising paragraph (d)(2)(ii)(A) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(A) For hospital-specific data, the hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(*1*) For the limited purpose of qualifying for geographic reclassification based on wage data from cost reporting periods beginning prior to FY 2000, a hospital may request that its wage data be revised if the hospital is in an urban area that was subject to the rural floor for the period during which the wage data the hospital wishes to revise were used to calculate its wage index.

(*2*) Once a hospital has accumulated at least 1 year of wage data in the

applicable 3-year average hourly wage period used by the MGCRB, the hospital is eligible to apply for reclassification based on those data.

* * * * *

■ 42. Section 412.278 is amended by revising paragraph (b)(1) to read as follows:

§ 412.278 Administrator's review.

* * * * *

(b) * * *

(1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. The hospital must also submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

* * * * *

■ 43. Section 412.312 is amended by adding paragraph (f) to read as follows:

§ 412.312 Payment based on the Federal rate.

* * * * *

(f) *Payment adjustment for certain clinical trial or expanded access use immunotherapy cases.* For discharges occurring on or after October 1, 2020, in determining the payment amount under this section for certain clinical trial or expanded access use immunotherapy cases as described in § 412.85(b), the DRG weighting factor described in paragraph (b)(1) of this section is adjusted as described in § 412.85(c).

■ 44. Section 412.523 is amended by adding paragraph (c)(3)(xvii) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xvii) *For long-term care prospective payment system fiscal year 2021 and subsequent fiscal years.* The long-term care hospital prospective payment system standard Federal payment rate for a long-term care hospital prospective payment system fiscal year is the standard Federal payment rate for the previous long-term care prospective payment system fiscal year updated by the percentage increase in the market basket index (as determined by CMS) less a multifactor productivity adjustment (as determined by CMS), and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

■ 45. Section 412.622 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 412.622 Basis of payment.

* * * * *

(b) * * *

(2) * * *

(i) Bad debts of Medicare beneficiaries, as provided in § 413.89 of this chapter; and

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 46. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 47. Section 413.20 is amended by revising paragraph (d)(3) to read as follows:

§ 413.20 Financial data and reports.

* * * * *

(d) * * *

(3)(i) The provider must furnish the contractor—

(A) Upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(B) Its median payer-specific negotiated charge by MS–DRG for payers that are Medicare Advantage (MA) organizations, as applicable, and changes thereto as they are put into effect.

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

* * * * *

■ 48. Section 413.79 is amended by adding paragraph (h)(1)(iii) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(h) * * *

(1) * * *

(iii) *Displaced resident* means a resident who—

(A) Leaves a program after the hospital or program closure is publicly announced, but before the actual hospital or program closure;

(B) Is assigned to and training at planned rotations at another hospital who will be unable to return to his/her rotation at the closing hospital or program;

(C) Is accepted into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program;

(D) Is physically training in the hospital on the day prior to or day of program or hospital closure; or

(E) Is on approved leave at the time of the announcement of closure or actual closure, and therefore, cannot return to his/her rotation at the closing hospital or program.

* * * * *

■ 49. Section 413.89 is amended by revising paragraphs (b)(1), (c), (e)(2), and (f) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(b) *Definitions*—(1) *Bad debts.* (i) For cost reporting periods beginning before October 1, 2020:

(A) ''Bad debts'' are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services.

(B) ''Accounts receivable'' and ''notes receivable'' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.

(ii) For cost reporting periods beginning on or after October 1, 2020, ''bad debts'' are amounts considered to be uncollectible from patient accounts that were created or acquired in providing services and are categorized as implicit price concessions for cost reporting purposes and are recorded in the provider's accounting records as a component of net patient revenue.

* * * * *

(c) *Normal accounting treatment: Reduction in revenue.* (1) For cost reporting periods beginning before October 1, 2020:

(i) Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services as these costs have already been incurred in the production of the services.

(ii) Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts.

(2) For cost reporting periods beginning on or after October 1, 2020:

(i) Bad debts, also known as ''implicit price concessions,'' charity, and

courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services as these costs have already been incurred in the production of the services.

(ii) Medicare bad debts must not be written off to a contractual allowance account but must be recorded as an implicit price concession that results in a reduction in revenue.

* * * * *

(e) * * *

(2) The provider must be able to establish that reasonable collection efforts were made.

(i) *Non-indigent beneficiary.* A non-indigent beneficiary is a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, nor have they been determined to be indigent by the provider for Medicare bad debt purposes. To be considered a reasonable collection effort for non-indigent beneficiaries, all of the following are applicable:

(A) A provider's collection effort or the effort of a collection agency acting on the provider's behalf, or both, to collect Medicare deductible or coinsurance amounts must consist of all of the following:

(*1*) Be similar to the collection effort put forth to collect comparable amounts from non-Medicare patients.

(*2*) For cost reporting periods beginning before October 1, 2020, involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary.

(*3*) For cost reporting periods beginning on or after October 1, 2020, involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following:

(*i*) The date of the Medicare remittance advice that results from processing the claim for services furnished to the beneficiary and generates the beneficiary's cost sharing amounts.

(*ii*) The date of the remittance advice from the beneficiary's secondary payer, if any.

(*iii*) The date of the notification that the beneficiary's secondary payer does not cover the service furnished to the beneficiary.

(*4*) Include other actions such as subsequent billings, collection letters, and telephone calls, emails, text messages, or personal contacts with this party.

(*5*)(*i*) Last at least 120 days after paragraph (e)(2)(i)(A)(*2*) or (*3*) of this section is met before being written off as uncollectible under paragraph (e)(3) of this section.

(*ii*) Start a new 120-day collection period each time a payment is received within a 120-day collection period.

(*6*) Maintaining and, upon request, furnishing verifiable documentation to its contractor that includes all of the following:

(*i*) The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients.

(*ii*) The patient account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.

(*iii*) The beneficiary's file with copies of the bill(s) and follow-up notices.

(B) A provider that uses a collection agency to perform its collection effort must do all of the following:

(*1*) Reduce the beneficiary's account receivable by the gross amount collected.

(*2*) Include any fee charged by the collection agency as an administrative cost.

(*3*) Before claiming the unpaid amounts as a Medicare bad debt, cease all collection efforts, including the collection agency efforts, and ensure that the collection accounts have been returned to the provider from the agency.

(ii) *Indigent non-dual eligible beneficiary.* An indigent non-dual eligible beneficiary is a beneficiary who is determined to be indigent or medically indigent by the provider and is not eligible for Medicaid as categorically or medically needy.

(A) To determine a beneficiary to be an indigent non-dual eligible beneficiary, the provider—

(*1*) Must not use a beneficiary's declaration of their inability to pay their medical bills or deductibles and coinsurance amounts as sole proof of indigence or medical indigence;

(*2*) Must take into account the analysis of both the beneficiary's assets (only those convertible to cash and unnecessary for the beneficiary's daily living) and income;

(*3*) May consider extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence which may include an analysis of both the beneficiary's liabilities and expenses, if indigence is unable to be determined under paragraph (e)(ii)(A)(*2*) of this section;

(*4*) Must determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill, such as a legal guardian or State Medicaid program; and

(*5*) Must maintain and, upon request, furnish its contractor its indigence policy describing the method by which indigence or medical indigence is determined and all the verifiable beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence.

(B) Once indigence is determined the bad debt may be deemed uncollectible without applying a collection effort under paragraph (e)(2)(i)(A) or (B) of this section.

(iii) *Indigent dual-eligible beneficiaries (including qualified Medicare beneficiaries).* Providers may deem Medicare beneficiaries indigent or medically indigent when such individuals have also been determined eligible for Medicaid under a State's Title XIX Medicaid program as either categorically needy individuals or medically needy individuals. To be considered a reasonable collection effort for dual-eligible beneficiaries:

(A) When a State permits a Medicare provider's Medicaid enrollment for the purposes of processing a beneficiary's claim, to determine the State's liability for the beneficiary's Medicare cost sharing, the provider—

(*1*) Must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible or coinsurance amounts;

(*2*) Must submit a bill to its Medicaid/Title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance;

(*3*) Must submit the Medicaid remittance advice received from the State to its Medicare contractor;

(*4*) Must reduce allowable Medicare bad debt by any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, regardless of whether the State actually pays its obligated amount to the provider; and

(*5*) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

(B) When, through no fault of the provider, a provider does not receive a Medicaid remittance advice because the State does not permit a Medicare provider's Medicaid enrollment for the purposes of processing a beneficiary's claim, or because the State does not generate a Medicaid remittance advice, the provider—

(*1*) Must submit to its contractor, all of the following auditable and verifiable documentation:

(*i*) The State's Medicaid notification stating that the State has no legal obligation to pay the provider for the beneficiary's Medicare cost sharing.

(*ii*) A calculation of the amount the State owes the provider for Medicare cost sharing.

(*iii*) Verification of the beneficiary's eligibility for Medicaid for the date of service;

(*2*) Must reduce allowable Medicare bad debt by any amount the State is obligated to pay, regardless of whether the State actually pays its obligated amount to the provider; and

(*3*) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

* * * * *

(f) *Reporting period for writing off bad debts and reporting of recoveries of bad debts reimbursed in prior periods.* For cost reporting periods beginning before, on, or after October 1, 2020, the deductible and coinsurance amounts uncollected from beneficiaries are to be written off and recognized as allowable bad debts in the cost reporting period in which the accounts are deemed to be worthless.

(1) Any payment on the account made by the beneficiary or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report.

(2) In some cases an amount written off as a bad debt and reimbursed by the program in a prior cost reporting period may be recovered in a subsequent period.

(i) In situations described in this paragraph (f)(2), the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered.

(ii) The amount of reduction in the period of recovery (as specified in paragraph (f)(2)(i) of this section) must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period.

* * * * *

■ 50. Section 413.355 is revised to read as follows:

§ 413.355 Additional payment: QIO reimbursement for cost of sending records electronically or by photocopy and mailing.

An additional payment is made to a skilled nursing facility in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 51. The authority citation for part 417 is revised to read as follows:

Authority: 42 U.S.C. 300e, 300e-5, 300e-91302 and 1395hh), and 31 U.S.C. 9701.

■ 52. Section 417.536 is amended by revising paragraph (g) to read as follows:

§ 417.536 Cost payment principles.

* * * * *

(g) *Charity and courtesy allowances.* As specified in § 413.89 of this chapter, charity and courtesy allowances are deductions from revenue and may not be included as allowable costs.

* * * * *

PART 476—QUALITY IMPROVEMENT ORGANIZATION REVIEW

■ 53. The authority citation for part 476 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 54. Section 476.78 is amended—

■ a. In paragraph (b)(2)(i) by removing the phrase ''photocopy and deliver to the QIO'' and adding in its place ''deliver to the QIO'';

■ b. By revising paragraphs (b)(2)(ii) and (c);

■ c. By redesignating paragraph (d) as paragraph (f);

■ d. By adding new paragraph (d) and paragraph (e); and

■ e. By revising newly redesignated paragraph (f).

The revisions and additions read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) * * *

(ii) Except if granted a waiver as described in paragraph (d) of this section, send secure transmission of an electronic version of each requested patient record to the QIO.

(A) Providers and practitioners must deliver electronic versions of patient records within 14 calendar days of the request.

(B) A QIO is authorized to require the receipt of the patient records earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and circumstances warrant earlier receipt of the patient records.

(C) A practitioner's or provider's failure to comply with the request for patient records within the established timeframe may result in the QIO taking action in accordance with § 476.90.

* * * * *

(c) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by

facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION INFORMATION

■ 55. The authority citation for part 480 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 56. Section 480.111 is amended by revising paragraph (d) to read as follows:

§ 480.111 QIO access to records and information of institutions and practitioners.

* * * * *

(d)(1) When submitting patient records to the QIO under this section, the institution or practitioner must do so consistent with the requirements in § 476.78(c) and (d) of this chapter.

(2) Reimbursement to an institution or practitioner for the cost of providing patient records is paid in accordance with § 476.78(e) of this chapter.

PART 484—HOME HEALTH SERVICES

■ 57. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 58. Section 484.265 is revised to read as follows:

§ 484.265 Additional payment.

An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 59. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 60. Section 495.4 is amended in the definition of ''EHR reporting period for a payment adjustment year'' by adding paragraphs (2)(vi) and (3)(vi) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(vi) The following are applicable for 2022:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2023 and 2024 payment adjustment years. For the FY 2023 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2022.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2024 payment adjustment year.

(3) * * *

(vi) The following are applicable for 2022:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2022 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2022 payment adjustment year.

* * * * *

§ 495.20 [Amended]

■ 61. Section 495.20 is amended—

■ a. In paragraph (e)(5)(iii) by removing the reference ''45 CFR 170.304(g)'' and adding in its place the reference ''45 CFR 170.314(g)''; and

■ b. In paragraph (l)(11)(ii)(C)(*1*) by removing the reference ''45 CFR 107.314(b)(2)'' and adding in its place the reference ''45 CFR 170.314(b)(2)''.

■ 62. Section 495.24 to be amended by revising paragraph (e)(5)(iii)(B) and the paragraph (e)(6)(ii)(B) subject heading to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(e) * * *

(5) * * *

(iii) * * *

(B) *Query of prescription drug monitoring program (PDMP) measure.* Subject to paragraph (e)(3) of this section, for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law. This

measure is worth 5 bonus points in CYs 2019, 2020, and 2021.

* * * * *

(6) * * *

(ii) * * *

(B) *Support electronic referral loops by receiving and reconciling health information measure.* * * *

* * * * *

■ 63. Section 495.104 is amended by revising paragraphs (c)(5)(viii)(B) through (D) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(c) * * *

(5) * * *

(viii) * * *

(B) ¾ for FY 2019;

(C) ½ for FY 2020; and

(D) ¼ for FY 2021.

* * * * *

Dated: August 31, 2020

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: September 1, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate of Increase- Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2020, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2020

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2021 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2021. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2020.

In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that will be applicable to Medicare LTCHs for FY 2021.

In general, except for SCHs and MDHs, for FY 2021, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section IV.G. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), for FY 2021, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, as we proposed, we are making we changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2021. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2021. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2021. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2021. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2021

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we used to use for determining the prospective payment rates for FY 2021.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2021, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the FY 2021 inpatient hospital update. The table that follows shows these four scenarios:

FY 2021 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS				
FY 2021	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.6	-0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.8	0	-1.8
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	0	0	0	0
Applicable Percentage Increase Applied to Standardized Amount	**2.4**	**0.6**	**1.8**	**0**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2021.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2020 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Public Law 114–255), are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- Beginning with FY 2021, as we proposed, we applied an adjustment to ensure the effects of the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), are budget neutral as required under section 108 of Public Law 116–94.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.N. of the preamble of this final rule).
- As discussed in this section and in section III.2.d of the preamble of this final rule, an adjustment to the standardized amount (using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act) to implement in a budget neutral manner our transition for hospitals negatively impacted due to changes to the wage index (including the implementation of the revised OMB market labor delineations). We refer reader to section III.2.d. of the preamble of this final rule, for a detailed discussion.
- An adjustment to remove the FY 2020 outlier offset and apply an offset for FY 2021, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2021, consistent with current law, as we proposed, we applied the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we applied a uniform, national budget neutrality adjustment to the FY 2021 wage index for the rural floor, as we proposed.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2021, as we proposed, we are continuing to use the national labor-related and nonlabor-related shares (which are based on the 2014-based hospital market basket) that were used in FY 2020. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2021, as discussed in section III. of the preamble of this final rule, as we proposed, we are continuing to use a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as we proposed, we applied the wage index to a labor-related share of 62

percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the internet on the CMS website.

Comment: A commenter asserted a calculation error regarding the treatment of transfers in setting the standardized amount in 1983 and that this alleged error impacts the FY 2021 standardized amount. This same commenter questioned if CMS had statutory authority to include transfers in the standardized amount for FY 2021.

Response: We disagree with the commenter. The calculations of the standardized amounts since the inception of the IPPS have proceeded through notice and comment rulemaking, and there have been numerous statutory changes to the standardized amounts in the intervening years since the inception of the IPPS. There is no basis for a change to the standardized amount now in FY2021.

Comment: Some commenters stated that CMS misinterpreted ATRA section 631 recoupment related to FY 2017, and that CMS should apply a MS–DRG documentation and coding positive adjustment of 0.7 percentage points in addition to the 0.5 percentage point adjustment proposed. Some commenters believed that would stop the continuation of a recoupment adjustment that no longer serves any recoupment purpose.

Response: We received similar comments on the ATRA requirements related to FY 2017 in response to the FY 2020 proposed rule, and we refer readers to that response. (84 FR 42057). In addition, we refer readers to section II.C of this final rule for additional discussion.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, as we proposed, we calculated the FY 2021 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, as we proposed, we used the 2014-based IPPS operating and capital market baskets for FY 2021. As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, as we proposed, we reduced the FY 2021 applicable percentage increase (which for this final rule is based on IGI's second quarter 2020 forecast of the 2014-based IPPS market basket) by the MFP adjustment, as discussed elsewhere in this final rule.

Based on IGI's second quarter 2020 forecast of the hospital market basket increase (as discussed in Appendix B of this final rule), the forecast of the hospital market basket increase for FY 2021 for this final rule is 2.4 percent. As discussed earlier, for FY 2021, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the FY 2021 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2021 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2021 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2021 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this final rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded- cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we adjusted the FY 2021 standardized amount to remove the effects of the FY 2020 geographic reclassifications and outlier payments before applying the FY 2021 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2021 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.
- The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single

payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2021, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42620), as we proposed, we are including all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, as we also proposed, we included all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

- Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2021, as we proposed, we are continuing to apply a proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2021 this would be FY 2020 final adjustment factors from Table 15 of the FY 2020 IPPS/LTCH final rule) and a proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2021 this would be FY 2020 final adjustment factors from Table 16B of the FY 2020 IPPS/LTCH final rule) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, as we proposed, we applied a proxy readmissions payment adjustment factor and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2021 (as we did for the last 7 fiscal years), as we proposed, we included estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this final rule and later in this section, we are continuing to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we included estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.G. of the preamble of this final rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, as we proposed, we continued to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- As we proposed, we included an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2021. Similar to FY 2020, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2021.
- In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2.b. of the preamble of this final rule.

We finally note that the wage index value is calculated and assigned to a hospital based on the hospital's labor market area. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). The current statistical areas used in FY 2020 are based on OMB standards published on February 28, 2013 (79 FR 49951) and Census 2010 data and Census Bureau population estimates for 2014 and 2015 (OMB Bulletin No. 17–01). As stated in section II.D.2. of the preamble to this final rule, on April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.* (We note, on March 6, 2020 OMB issued OMB Bulletin 20–01 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*), and as discussed in the preamble, this bulletin was not issued in time for development of the FY 2021 IPPS/LTCH PPS proposed rule.)

In section III.A.2. of the preamble to this final rule, as we proposed, we are implementing the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020

beginning with the FY 2021 IPPS wage index. Consistent with our adoption of the revised OMB delineations, in order to properly determine aggregate payments on each side of the comparison for our budget neutrality calculations, as we proposed, we used wage indexes based on the new OMB delineations in the determination of all of the budget neutrality factors discussed in this section. We also note that, consistent with past practice as finalized in the FY 2005 IPPS final rule (69 FR 49034), we are not adopting the revised OMB delineations themselves in a budget neutral manner. We continue to believe that the revision to the labor market areas in and of itself does not constitute an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

a. Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, as we proposed, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2021, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2020 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2020 relative weights, and the FY 2020 pre-reclassified wage data, and applied the FY 2021 hospital readmissions payment adjustments and estimated FY 2021 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2020 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, and the FY 2020 pre-reclassified wage data, and applied the FY 2021 hospital readmissions payment adjustments and estimated FY 2021 hospital VBP payment adjustments applied previously. (We note that these FY 2021 relative weights reflect our temporary measure for FY 2021, as discussed in section II.G. of the preamble of this final rule, to set the FY 2021 relative weight for MS–DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 relative weight). Because this payment simulation uses the FY 2021 relative weights, consistent with our policy in section IV.I. of the preamble to this final rule, we applied the adjustor for certain CAR T-cell therapy cases in our simulation of these payments. (As discussed in section II.E.2.b. of the preamble of this final rule, we also calculated an adjustment to account for certain CAR T-cell therapy cases in calculating the FY 2021 relative weights and for purposes of budget neutrality and outlier simulations.) We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2021 relative weights, as we proposed, we applied the adjustor for certain CAR T-cell therapy cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this final rule for a complete discussion on the adjustor for certain CAR T-cell therapy cases and to section II.E.2.b. of the preamble of this final rule, for a complete discussion of the adjustment to the FY 2021 relative weights to account for certain CAR T-cell therapy cases.

Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we proposed, we applied the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2020. Please see the table later in this section setting forth each of the FY 2021 budget neutrality factors.

Comments: Some commenters requested that CMS revisit the MS–DRG recalibration process to determine reasons for negative impacts on rural hospitals generally, and hospitals designated as RRCs, SCHs, and MDHs based on the proposed rule's impact table and past final rules' table. Some commenters requested a special adjustment to prevent significant losses from the MS–DRG recalibration process, which the commenters asserted has had an ongoing negative impact.

Response: We thank the commenters for their input and suggestion. For a discussion of the estimated impact table, we refer the reader to the Appendix of this final rule. For this final rule, as noted previously, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met. We believe we have applied this budget neutrality adjustment appropriately.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2021, as we proposed, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights and the FY 2020 pre-reclassified wage indexes, applied the FY 2020 labor-related share of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the FY 2021 hospital readmissions payment adjustment and the estimated FY 2021 hospital VBP payment adjustment; and
- Aggregate payments using the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights and the FY 2021 pre-reclassified wage indexes, applied the labor-related share for FY 2021 of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same FY 2021 hospital readmissions payment adjustments and estimated FY 2021 hospital VBP payment adjustments applied previously.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2020 to FY 2021. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2021 budget neutrality factors.

c. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, as finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42333 through 42336), we excluded the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located.'' We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2021, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, and the FY 2021 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, and the FY 2021 wage data after such reclassifications, and applied the same FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2021, and applies the policies explained in section III. of the preamble of this final rule. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the FY 2021 budget neutrality factors.

The FY 2021 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2020 budget neutrality adjustment factor. We note that the FY 2021 budget neutrality adjustment reflects FY 2021 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule.

d. Rural Floor—Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index. We note, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42332 through 42336), for FY 2021 we are calculating the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103).

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2021, as we proposed, we calculated a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2021 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2021 rural Puerto Rico wage index is calculated based on the average of the FY 2021 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2019 discharge data to simulate payments, the revised OMB labor market area delineations for FY 2021 and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor; and
- National simulated payments with the rural floor.

Based on this comparison, we determined a national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2021 budget neutrality factors.

Comment: A commenter opposed the application of the nationwide rural floor budget neutrality adjustment

Response: In accordance with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are required to apply a uniform, national budget neutrality adjustment to the FY 2021 wage index for the rural floor.

e. Rural Community Hospital Demonstration Program Adjustment

In section IV.O. of the preamble of this final rule, we discuss the Rural Community Hospital Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). We make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section IV.O. of the preamble of this final rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2021, based on the latest data for this final rule, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $39,825,670.Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2021, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that will be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2021 budget neutrality factors. We refer readers to section IV.O. of the preamble of this final rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

f. Stem Cell Acquisition Reasonable Cost Based Payment Budget Neutrality Adjustment

In section IV.H. of the preamble of this final rule, we discuss the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs beginning in FY 2021. Section 108 of the Further Consolidated Appropriations Act, 2020 requires that, for cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant, payment to such hospital for

hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner. That is, under section 1886(d)(4)(C)(iii) of the Act as amended by section 108 of the Further Consolidated Appropriations Act, 2020, beginning with FY 2021, the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are to be made in a manner that assures that the aggregate IPPS payments for discharges in the fiscal year are not greater or less than those that would have been made without such payments. With regard to budget neutrality, we proposed to make an adjustment to the standardized amount to ensure the effects of the reasonable cost-based payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, as required under section 1886(d)(4)(C)(iii) of the Act as amended by section 108 of Public Law 116–94. For FY 2021, based on the most recent data available for the proposed rule, the total amount that we proposed to apply to make an adjustment to the standardized amounts to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral was $15,865,374. Using the more recent data available for this final rule, we updated the total amount to $16,167,790.60. Accordingly, for FY 2021 we computed a final budget neutrality adjustment that we applied to the standardized amounts for FY 2021. Please see the table later in this section setting forth each of the FY 2021 budget neutrality factors. We refer readers to section IV.H. of the preamble of this final rule for further details regarding the calculation of the estimated amount of reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs that we are using to make an adjustment to the standardized amount for FY 2021.

g. Continuation of the Low Wage Index Hospital Policy—Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this final rule, we are continuing the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in the FY 2020 IPPS/LTCH final rule (84 FR 42332), consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are making a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this budget neutrality adjustment factor for FY 2021, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, and the FY 2021 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy but without the 5 percent cap, and applied the FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section; and
- Aggregate payments using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, and the FY 2021 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy but without the 5 percent cap, and applied the same FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

This FY 2021 budget neutrality adjustment factor was applied to the standardized amount. Please see the table later in this section setting forth each of the FY 2021 budget neutrality factors.

For a discussion of public comments on this policy, we refer the reader to section III.G.3. of the preamble of this final rule.

h. Transition Budget Neutrality Adjustment

In section III.A.2. of the preamble to this final rule, as we proposed, we are implementing the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. As we further stated in section III.A.2. of the preamble of this final rule, while the revised OMB delineations in the OMB bulletin (OMB Bulletin 18–04) are not based on new census data, there were some material changes in the OMB delineations. In accordance with our past practice of implementing transition policies to help mitigate negative impacts on hospitals of certain wage index policies, we stated that, in adopting the revised OMB delineations, it would be appropriate to implement a transition policy since, as mentioned previously, some of these revisions are material, and may negatively impact payments to hospitals. As we stated in section III.A.2. of the preamble of this final rule, we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year, as we did for FY 2020, is an appropriate transition for FY 2021 for the revised OMB delineations. We refer the reader to section III.A.2. of the preamble to this final rule for a complete discussion on the rationale of this transition.

For FY 2021, as we proposed, we are using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our transition for hospitals negatively impacted is implemented in a budget neutral manner. We refer readers to section III.A.2. of the preamble of this final rule for a complete discussion regarding this policy. To calculate a transition budget neutrality adjustment factor for FY 2021, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, the FY 2021 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage; and
- Aggregate payments with the 5-percent cap using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations for FY 2021, the FY 2021 relative weights, the FY 2021 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the same FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage.

This FY 2021 budget neutrality adjustment factor was applied to the standardized amount. Please see the table later in this section setting forth each of the FY 2021 budget neutrality factors.

For a discussion of the public comments on this policy, we refer the reader to section III.A.2.C. and d. of the preamble of this final rule.

We note, Table 2 associated with this final rule, which is available via the internet on the CMS website contains the wage index by provider before and after applying the low wage index hospital policy and the transition.

Summary of FY 2021 Budget Neutrality Factors	
MS-DRG Recalibration Budget Neutrality Factor	0.997980
Wage Index Budget Neutrality Factor	1.000426
Reclassification Budget Neutrality Factor	0.986583
*Rural Floor Budget Neutrality Factor	0.993433
Rural Demonstration Budget Neutrality Factor	0.999626
Stem Cell Acquisition Budget Neutrality Factor	0.999848
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998835
Transition Budget Neutrality Factor	0.998015

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

i. Adjustment for FY 2021 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2021, as we proposed, we are implementing the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

j. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2021 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2021, as we proposed, we incorporated an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm.*

(1) Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2020 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital will owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS will owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2021, we finalized a methodology to incorporate outlier reconciliation in the FY 2021 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Projection of Outlier Payment Reconciliations for the FY 2021 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2021, as we proposed, we are continuing to incorporate

outlier reconciliation in the FY 2021 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a complete discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation.

In the FY 2020 IPPS/LTCH PPS final rule, we stated that the methodology for FY 2020 could advance by 1 year the cost reports used to determine the historical outlier reconciliation. In the proposed rule, to determine a projection of outlier payment reconciliations for the FY 2021 outlier threshold calculation, we proposed to advance the methodology by 1 year and use FY 2015 cost reports (cost reports with a begin date on or after October 1, 2014, and on or before September 30, 2015).

For FY 2021, we proposed to use the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2021 outlier threshold calculation. The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2021:

Step 1.—Use the Federal FY 2015 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2015 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2015 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2015. This percentage amount would be used to adjust the outlier target for FY 2021 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we proposed to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2015 cost reports based on the December 2019 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, but the percentage determined in Step 4 rounds to 0, we stated that we are targeting 5.1 percent for outlier payments for FY 2021 under our proposed methodology.

In the FY 2021 proposed rule, we used the December 2019 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2021 final rule, we proposed to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2021, would be the March 2020 extract. Similar to the FY 2020 final rule, we stated that we might also consider the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2021 outlier threshold.

In the FY 2021 proposed rule, based on the December 2019 HCRIS, 16 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $2,516,904 (Step 2). The total Federal operating payments based on the December 2019 HCRIS was $90,313,815,275 (Step 3). The ratio (Step 4) is a negative 0.002787 percent, which, when rounded to the second digit, is 0.00 percent. Therefore, for FY 2021, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.10 percent [5.1 percent − (−.00 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of the Addendum to the proposed rule, we provided the FY 2021 outlier threshold as calculated for the proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation. However, we noted that for the proposed rule, the outlier threshold was the same with and without the percentage estimate, since the projection of outlier reconciliation rounded to zero.

As explained in the FY 2020 IPPS/LTCH PPS final rule, we proposed to continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond three decimals). However, under our methodology, we believe a three decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the unrounded six decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we proposed to determine an outlier adjustment by applying a factor to the standardized amount that accounts for the projected proportion of total estimated FY 2021 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2021 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2021 would be the sum of the estimated FY 2021 outlier payments based on the claims data from the outlier model and the estimated FY 2021 total operating outlier reconciliation dollars. We stated that we believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2021 operating Federal payments paid as outliers. In other words, the net effect of our outlier proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2021 outlier payments (which included the proposed estimated recoupment percentage for FY 2021 of 0.00 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the proposed operating outlier offset to the standardized amount was 0.949 (1 − 0.051).

We invited public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2021.

Comment: A commenter supported incorporating an estimate of outlier reconciliation. A commenter stated that they were successful in replicating the proposed calculations given the logic described. Based on the commenter's analysis, the commenter determined that no adjustment for FY 2021 is necessary based on their analysis of historical cost report data.

Response: We thank the commenter for their feedback on the proposed calculation methodology.

After consideration of the comments received, and for the reasons discussed in the proposed rule and in this final rule, we are finalizing the methodology described previously for incorporating the outlier reconciliation in the outlier threshold calculation. Therefore, for this final rule we

used the same steps described previously and in the proposed rule to incorporate a projection of operating outlier payment reconciliations for the calculation of the FY 2021 outlier threshold calculation. The March 2020 HCRIS contained data for 17 hospitals. As stated previously, while we proposed to use the March 2020 HCRIS extract to calculate the reconciliation adjustment for this FY 2021 IPPS final rule, we also stated that similar to the FY 2020 final rule, we might consider the use of more recent data that may become available for purpose of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2021 outlier threshold. Data for two additional outlier reconciliations were made available to CMS outside of the March 2020 HCRIS update. Similar to our discussion of the estimated operating outlier reconciliation for FY 2020 in the FY 2020 IPPS/LTCH final rule (84 FR 53609), we believe supplementing with two hospitals' outlier reconciliation data will lend additional accuracy to project the estimate of operating outlier reconciliation used in the calculation of the outlier threshold. Therefore, in order to use the most complete data for FY 2015 cost reports, we are using the March 2020 HCRIS extract, supplemented by these two additional hospitals' data this FY 2021 IPPS final rule. Without the two additional hospitals' data, the rounded operating outlier reconciliation percentage would have been 0 (unrounded of 0.004506). As we gain more experience with this policy, we also are considering adding additional lines to the cost report in order to ensure we capture the maximum cost report data with the March HCRIS extract to calculate the percentage adjustment for outlier reconciliation. For the final rule for future rulemaking, as we generally expect historical cost reports for the applicable fiscal year to be available by March. Based onMarch 2020 HCRIS and supplemental data for two hospitals, a total of 19 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $8,650,344 (Step 2). The total Federal operating payments based on the March 2020 HCRIS is $90,321,677,004 (Step 3). The ratio (Step 4) is a negative 0.009577 percent, which, when rounded to the second digit, is negative 0.01 percent. Therefore, for FY 2021, using the finalized methodology, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (−0.01 percent)]. As noted previously, when the percentage of operating outlier reconciliation dollars to total Federal operating payments is negative (such is the case when the aggregate amount of outlier reconciliation is negative), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum of this final rule, we provide the FY 2021 outlier threshold as calculated both with and without including this percentage estimate of operating outlier reconciliation.

(b) Reduction to the FY 2021 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we proposed to reduce the FY 2021 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2021, we proposed to use the same methodology from FY 2020 to adjust the FY 2021 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposal for FY 2021 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also proposed to adjust our estimate of FY 2021 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. To do so, we proposed to use the following methodology, which generally parallels the methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2021 outlier threshold calculation.

Step 1.—Use the Federal FY 2015 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule. We used the December 2019 HCRIS extract for the proposed rule and stated that we expected to use the March 2020 HCRIS extract for the FY 2021 final rule. Similar to the FY 2020 final rule, we stated that we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2021 adjustment to the FY 2021 capital standard Federal rate.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2015 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2015 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2015. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2021 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we proposed that the estimate of capital outlier payments for FY 2021 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments.

We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, we stated that the estimate of capital outlier payments

for FY 2021 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

Similarly, for the FY 2021 proposed rule, we used the December 2019 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2021 final rule, we proposed to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2021, would be the March 2020 extract. As previously noted, we stated that we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2021 adjustment to the FY 2021 capital standard Federal rate.

For the FY 2021 proposed rule, the estimated percentage of FY 2021 capital outlier payments otherwise determined using the shared outlier threshold was 5.42 percent (estimated capital outlier payments of $432,102,494 divided by (estimated capital outlier payments of $432,102,494 plus the estimated total capital Federal payment of $7,569,294,589)). Based on the December 2019 HCRIS, 16 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $956,065 (Step 2). The total Federal capital payments based on the December 2019 HCRIS was $8,114,838,772 (Step 3) which results in a ratio (Step 4) of −0.01 percent. Therefore, for FY 2021, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2021 aggregate capital outlier payments by 0.01 percent.

As discussed in section III.A.2. of this Addendum, we proposed to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2021.

We are invited public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2021 capital outlier payments for purposes of determining the capital outlier adjustment factor.

We did not receive comments about the proposed capital outlier reconciliation methodology.

For the reasons discussed, we are finalizing the methodology for projecting an estimate of capital outlier reconciliation. Therefore, for this final rule we used the same steps as described in the proposed rule and this final rule to reduce the FY 2021 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers.

For projecting the estimate of capital outlier reconciliation, similar to our projection of the estimate of operating outlier reconciliation, we are using cost report data of 17 hospitals from the March 2020 HCRIS supplemented for two hospitals for a total of 19 hospitals, which we believe will lend additional accuracy to the projection of estimated capital outlier reconciliation for FY 2021. Without the two additional reports, the step 4 unrounded value for capital outlier reconciliation would have been 0.0152, which rounds to 0.02. We note that a difference in the number of cost reports for the operating and capital outlier reconciliation projections is possible and may be due to new hospitals defined in the regulations at 42 CFR 412.300(b) that may receive capital cost-based payments (in lieu of Federal rate payments), and therefore would not receive capital outlier payments. As a result, capital outlier reconciliation is not applicable to such hospitals since there is no capital outlier payment.

The estimated percentage of FY 2021 capital outlier payments otherwise determined using the shared outlier threshold is 5.36 percent (estimated capital outlier payments of $429,431,834 divided by (estimated capital outlier payments of $429,431,834 plus the estimated total capital Federal payment of $7,577,697,269)). Based on the March 2020 HCRIS supplemented by the data for two additional providers, 19 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $1,901,335 (Step 2). The total Federal capital payments based on the March 2020 HCRIS and supplemental two reports is $8,114,957,508 (Step 3). The ratio (Step 4) is a negative 0.023430 percent, which, when rounded to the second digit, is negative 0.02 percent (Step 4). Therefore, for FY 2021, taking into account projected capital outlier reconciliation payments under our methodology would decrease the estimated percentage of FY 2021 aggregate capital outlier payments by 0.02 percent.

(2) FY 2021 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the FY 2021 outlier threshold, we simulated payments by applying FY 2021 payment rates and policies using cases from the FY 2019 MedPAR file.

We note that because this payment simulation uses the FY 2021 relative weights, consistent with our finalized policy discussed in section IV.I. of the preamble to this final rule, we applied the adjustor for certain CAR–T cell therapy cases in our simulation of these payments. As discussed in section II.E.2.b. of the preamble of this final rule, we are finalizing an adjustment to account for certain CAR T-cell therapy cases in calculating the FY 2021 relative weights and for purposes of budget neutrality and outlier simulations. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the FY 2021 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2019 to FY 2021. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we proposed to use the following methodology to calculate the charge inflation factor for FY 2021:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years (for example, FY 2019 to FY 2021).

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we

believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change. For the same reasons discussed in that rulemaking, for FY 2021, we proposed to use the same methodology as FY 2020 and advance by 1 year the MedPAR data used to determine the charge inflation factor. That is, for FY 2021, we proposed to use the MedPAR files for the two most recent available federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for the proposed rule we used the December 2018 MedPAR file of FY 2018 (October 1, 2017 to September 30, 2018) charge data (released for the FY 2020 IPPS/LTCH PPS proposed rule) and the December 2019 MedPAR file of FY 2019 (October 1, 2018 to September 30, 2019) charge data (released for the FY 2021 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We proposed that for the FY 2021 final rule, we would use more recently updated data, that is the MedPAR files from March 2019 for the FY 2018 time period and March 2020 for the FY 2019 time period. Under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case for FY 2021, we compared the average covered charge per case of $61,533.34 ($582,022,123,240/9,458,647 cases) from October 1, 2017, through September 30, 2018 to the average covered charge per case of $65,442.49 ($601,183,502,371/9,186,440 cases) from October 1, 2018 through September 30, 2019. This rate-of-change was 6.4 percent (1.06353) or 13.1 percent (1.131096) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to establish the FY 2021 outlier threshold using hospital CCRs from the December 2019 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of the proposed rule. We proposed to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2021, we also proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We also proposed that, if more recent data become available, we would use that data to calculate the final FY 2021 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done since FY 2014, we proposed to adjust the CCRs from the December 2019 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2018 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2019 update of the PSF. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this will produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for the proposed rule, we calculated a proposed December 2018 operating national average case-weighted CCR of 0.255979 and a proposed December 2019 operating national average case-weighted CCR of 0.249649. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2018 operating national average case-weighted CCR from the December 2019 operating national average case-weighted CCR and then dividing the result by the December 2018 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.975271.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2018 capital national average case-weighted CCR of 0.021043 and a December 2019 capital national average case-weighted CCR of 0.020255. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2018 capital national average case-weighted CCR from the December 2019 capital national average case-weighted CCR and then dividing the result by the December 2018 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.962553.

For purposes of estimating the proposed outlier threshold for FY 2021, we used a wage index that reflects the policies discussed in the proposed rule. This includes the proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act, the proposed out-migration adjustment as added by section 505 of Public Law 108–173, as well as incorporating the FY 2021 wage index adjustment for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We also incorporated our proposal of the 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020. We stated in the proposed rule that if we did not take the aforementioned into account, our estimate of total FY 2021 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections IV.K. and IV.L., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the proposed hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We noted in the proposed rule that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2021, we also proposed to allocate an estimated per-discharge uncompensated care

payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2021, we proposed to include estimated FY 2021 uncompensated care payments in the computation of the outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we proposed to incorporate an estimate of FY 2021 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2021 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) was a negative 0.002787 percent, which, when rounded to the second digit, is 0.00 percent. Therefore, for FY 2021, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.10 percent [5.1 percent − (−.00 percent)]. Under the proposed approach, we determined a threshold of $30,006 and calculated total outlier payments of $4,935,261,570 and total operating Federal payments of $91,833,641,321. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.10 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). Since the target remained at 5.10 percent, we noted that the threshold calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold is the same as identified previously at $30,006. We proposed an outlier fixed-loss cost threshold for FY 2021 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $30,006.

Comment: Regarding the proposed charge inflation methodology, a commenter stated that relying on FYs 2018 and 2019 charge data was a thoughtful choice for the proposed rule, but did not believe that less current data should be used for the final rule. This commenter asserted that CMS should disclose all aspects of its edits to the most current data and commit to the same process and methods when it recalculates the threshold for purposes of the final rule. A commenter stated that their analysis using the publically available claim data, was 6.404 percent in comparison to the proposed rule's 6.353 percent for charge inflation.

Response: We thank the commenter for their input and analysis. We have not made any modification to the proposed charge inflation methodology in this final rule, other than using more recently updated data. In addition, we refer the reader to the detailed discussion in last year's final rule regarding the use of publically available data in the charge inflation methodology initially adopted in the FY 2020 IPPS final rule (84 FR 42627).

Comment: Commenters expressed concerns with the increase of the outlier threshold from $26,473 in FY 2020 to $30,006 in the FY 2021 proposed rule. They asserted that the increase will reduce the number of Medicare inpatient cases that qualify for an outlier payment. Some commenters recommended that CMS maintain the current threshold of $26,473. A commenter requested CMS examine the reasons for the continuing rise in the outlier threshold and whether there are any interventions CMS can take to ensure that outlier payments remain equitable and continue to protect hospitals from high cost cases where Medicare payments are insufficient to adequately compensate.

Response: As noted previously, section 1886(d)(5)(A)(iv) of the Act states that outlier payments may not be not less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year. We believe that maintaining the FY 2020 outlier fixed-loss cost threshold for FY 2021 would be inconsistent with the statute because we would be setting a threshold based on the prior fiscal year. Also, when we calculate the threshold, we use the updated data that is available at the time of the development of the proposed and final rule.

Comment: Some commenters requested that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. One commenter explained that high charge cases have a significant impact on the threshold. The commenter observed that the amount of cases with over $1.5 million in covered charges has increased significantly from FY 2011 (926 cases) to FY 2019 (3,062 cases). The commenter believed that the impact of these cases will cause the threshold to rise and recommended that CMS carefully consider what is causing the trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, and whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs.

Response: As we explained when responding to a similar comment in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526), the methodology used to calculate the outlier threshold includes all claims in order to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We believe excluding these cases would artificially lower the threshold. We believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we believe the inclusion of the high-cost outlier cases in the calculation of the outlier threshold is appropriate.

Comment: A commenter noted that, for a given year, typically the final outlier threshold established by CMS in the final rule is lower than the threshold set forth in the proposed rule. The commenter emphasized that CMS should use the most recent data available when the Agency calculates the outlier threshold.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer readers to that rule for our response. We note that we have updated at the time of development of this final rule to use more recent data available (that is, the March 2020 release of MedPAR claims from FY 2019).

After consideration of the public comments we received, we are using the same methodology we proposed to calculate the final outlier threshold. As discussed previously, we are adopting for this final rule to calculate charge inflation using the publically available FY 2018 and FY 2019 claims data and to incorporate a projection of outlier payment reconciliations for the FY 2021 outlier threshold calculation.

For the FY 2021 final outlier threshold, we used the used the March 2019 MedPAR file of FY 2018 (October 1, 2017 through September 30, 2018) charge data (released in conjunction with the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018 through September 30, 2019) charge data (released in conjunction with this FY 2021 IPPS/LTCH PPS final rule) to determine the charge inflation factor. To compute the 1 year average annual rate of change in charges per case, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017 through September 31, 2018, to the average covered charge per case of $65,522.10 ($604,209,834,327/9,519,120 cases) from October 1, 2018 through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 13.2 percent (1.13218) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, we are establishing the FY 2021 outlier threshold using hospital CCRs from the March 2020 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of the final rule. We applied the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described below to hospitals assigned the statewide average CCR. For FY 2021, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below).

For this final rule, as we have done since FY 2014, we are adjusting the CCRs from the March 2020 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the methodology described previously, for this final rule, we calculated a March 2019 operating national average case-weighted CCR of 0.254027 and a March 2020 operating national average case-weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.974495.

We used the same methodology to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.96165.

As discussed previously, similar to the proposed rule, for FY 2021, we applied the following policies (as discussed in more detail earlier):

- We used a wage index based on the FY 2021 wage index that hospitals will be paid. This included our policy to remove urban to rural reclassifications from the calculation of the rural floor, the frontier State floor adjustment in accordance with section 10324(a) of the Affordable Care Act, and the out migration adjustment as added by section 505 of Public Law 108–173, and incorporates our wage index policies to: (1) Increase the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals, and (2) apply a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index in FY 2020. As stated previously, if we did not take the above into account, our estimate of total FY 2021 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.11 percent of total payments (which reflects the estimate of outlier reconciliation calculated for this final rule).
- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are finalizing to incorporate an estimate of FY 2021 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this FY 2021 final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.009217 percent, which, when rounded to the second digit, is 0.01 percent. Therefore, for FY 2021, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (− .01 percent)]. Under this approach, we determined a threshold of $29,051 and calculated total outlier payments of $4,955,813,978 and total operating Federal payments of $92,027,177,037. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.11 percent target, which reflects our methodology to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our finalized methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the threshold would have been $29,108. We are finalizing an outlier fixed-loss cost threshold for FY 2021 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $29,051.

(3) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2021 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) will result in outlier payments that will equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments will equal 5.34 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we reduced the FY 2021 standardized amount by the percentage of 5.1 percent to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2021 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.946569

*The adjustment factor for the capital federal rate includes an adjustment to the estimated percentage of FY 2021 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III. A. 2 in the Addendum of this final rule.

We are applying the outlier adjustment factors to the FY 2021 payment rates after removing the effects of the FY 2020 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.142 or capital CCRs greater than 0.135, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2020 and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B would be used during FY 2021 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2019 Outlier Payments

Our current estimate, using available FY 2019 claims data, is that actual outlier payments for FY 2019 were approximately 5.43 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2019, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2019. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2019 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2020 period will not be available until after September 30, 2020, we are unable to provide an estimate of actual outlier payments for FY 2020 based on FY 2020 claims data in this final rule. We will provide an estimate of actual FY 2020 outlier payments in the FY 2022 IPPS/LTCH PPS proposed rule.

5. FY 2021 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2021. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 68.3 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2021.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2021 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2020 national standardized amounts to the FY 2021 national standardized amounts. The second through fifth columns display the changes from the FY 2019 standardized amounts for each applicable FY 2021 standardized amount. The first row of the table shows the updated (through FY 2020) average standardized amount after restoring the FY 2020 offsets for outlier payments and the geographic reclassification budget neutrality. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2020 adjustment factors are not removed from this table. Additionally, for FY 2021 we have applied the budget neutrality factors for the low wage index hospital policy and the transition policy, described previously.

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CHANGES FROM FY 2020 STANDARDIZED AMOUNTS TO THE FY 2021 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2021 Base Rate after removing: 1. FY 2020 Geographic Reclassification Budget Neutrality (0.985447) 2. FY 2020 Operating Outlier Offset (0.949)	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59
3. FY 2020 Rural Demonstration Budget Neutrality Factor (0.999771) 4. FY 2020 Lowest Quartile Budget Neutrality Factor (0.997894) 5. FY 2020 Transition Budget Neutrality Factor (0.998835)	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,856.11 Nonlabor (38%): $2,363.43	If Wage Index is less Than or Equal to 1.0000: Labor (62%) $3,856.11 Nonlabor (38%): $2,363.43	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,856.11 Nonlabor (38%): $2,363.43	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,856.11 Nonlabor (38%): $2,363.43
FY 2021 Update Factor	1.024	1.006	1.0180	1
FY 2021 MS-DRG Recalibration Budget Neutrality Factor	0.997980	0.997980	0.997980	0.997980
FY 2021 Wage Index Budget Neutrality Factor	1.000426	1.000426	1.000426	1.000426
FY 2021 Reclassification Budget Neutrality Factor	0.986583	0.986583	0.986583	0.986583
FY 2021 Rural Demonstration Budget Neutrality Factor	0.999626	0.999626	0.999626	0.999626
FY 2021 Stem Cell Acquisition Budget Neutrality Factor	0.999848	0.999848	0.999848	0.999848
FY 2021 Low Wage Index Hospital Policy Budget Neutrality Factor	0.998835	0.998835	0.998835	0.998835
FY 2021 Transition Budget Neutrality Factor	0.998015	0.998015	0.998015	0.998015
FY 2021 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2021 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
National Standardized Amount for FY 2021 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7)	**Labor: $4,071.49** **Nonlabor: $1,889.70**	**Labor: $3,999.92** **Nonlabor: $1,856.48**	**Labor: $4,047.63** **Nonlabor: $1,878.63**	**Labor: $3,976.06** **Nonlabor: $1,845.41**
National Standardized Amount for FY 2021 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,695.94** **Nonlabor: $2,264.25**	**Labor: $3,630.97** **Nonlabor: $2,225.43**	**Labor: $3,674.28** **Nonlabor: $2,251.98**	**Labor: $3,609.31** **Nonlabor: $2,212.16**

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B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor related and -nonlabor related-shares that we used to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2021. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2021, as discussed in section IV.B.3. of the preamble of this final rule, as we proposed, we are applying a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as we proposed, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2021 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). For FY 2018, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530 through 38531), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, as we proposed, we are continuing to use the same COLA factors in FY 2021 that were used in FY 2019 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The following table lists the COLA factors for FY 2021.

FY 2021 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of Living Adjustment Factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur at the same time as the update to the labor-related share of the IPPS market basket (no later than FY 2022).

C. Calculation of the Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2021

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2021 equals the Federal rate (which includes uncompensated care payments).

Under current law, the MDH program has been extended for discharges occurring through September 30, 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (which, as discussed in section V.G. of the preamble of this final rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2021 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for FY 2021 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition,

charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))
—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (1 + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)
—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)
—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount
—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)
—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)
—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor
—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted previously, the MDH program has been extended under current law for discharges occurring through September 30, 2022. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2021

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.6	-0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.8	0	-1.8
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	0	0	0	0
Applicable Percentage Increase Applied to Standardized Amount	**2.4**	**0.6**	**1.8**	**0**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this final rule. In addition, because SCHs and MDHs use the same MSDRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the -hospital specific-rate is adjusted by a budget

neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or an MDH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2020. We note that, in this final rule, for FY 2021, we are not making a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this final rule for a complete discussion regarding our policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2021

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we used to determine the capital Federal rate for FY 2021, which are effective for discharges occurring on or after October 1, 2020.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals.

Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2021

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2021. In particular, we explain why the FY 2021 capital Federal rate would increase approximately 0.84 percent, compared to the FY 2020 capital Federal rate. As discussed in the impact analysis in Appendix A to this FY 2021 IPPS/LTCH final rule, we estimate that capital payments per discharge would increase approximately 0.3 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2021 under that framework is 1.1 percent based on a projected 1.1 percent increase in the 2014-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2021 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we applied in the update framework for FY 2021.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2021, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2021. The net adjustment for change in case-mix is the difference between the projected real increase in case mix and the projected total increase in case mix. Therefore, as we proposed, the net adjustment for case-mix change in FY 2021 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2019 DRG reclassification and recalibration as part of our update for FY 2021. We assume, for purposes of this adjustment, that the estimate of FY 2019 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, as we proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2021.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.0

percentage point was calculated for the FY 2019 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2019 CIPI (1.4 percent) used in calculating the FY 2019 update factor was the same percentage increase as the actual realized price increase (1.4 percent). As this does not exceed the 0.25 percentage point threshold, we are not making an adjustment for forecast error in the update for FY 2021.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, as we proposed, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2021 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2021, we used an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2014 and extending through FY 2018. Based on these data, we estimated that case-mix constant intensity declined during FYs 2014 through 2018. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2021. Therefore, as we proposed, we made a 0.0 percentage point adjustment for intensity in the update for FY 2021.

Earlier, we described the basis of the components we used to develop the 1.1 percent capital update factor under the capital update framework for FY 2021, as shown in the following table.192

FY 2021 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.1
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	-0.5
Subtotal	1.1
Effect of FY 2019 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	1.1

*The capital input price index represents the 2014-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2021, as we proposed we are incorporating the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2020. (For more details on our policy to incorporate outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this final rule.)

For FY 2020, we estimated that outlier payments for capital-related PPS payments would equal 5.37 percent of inpatient capital-related payments based on the capital Federal rate in FY 2020. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 5.36 percent for inpatient capital-related payments based on the capital Federal rate in FY 2021. However, using the methodology outlined in section II.A. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease FY 2021 aggregate estimated capital outlier payments by 0.02 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.34 percent (5.36 percent − 0.02 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2021. Accordingly, we applied an outlier adjustment factor of 0.9466 in determining the capital Federal rate for FY 2021. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2021 would be lower than the percentage for FY 2020.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2021 outlier adjustment of 0.9466 is a 0.03 percent change from the FY 2020 outlier adjustment of 0.9463. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2021 is 1.0003 (0.9466/0.9463; calculation performed on unrounded numbers) so that the outlier adjustment will increase the FY 2021 capital Federal rate by approximately 0.03 percent compared to the FY 2020 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based

on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this final rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values. As also discussed in section III.G.3. of the preamble of this final rule, this policy will continue in FY 2021. In addition, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). Therefore, as mentioned in section III.G.1. of the preamble of this final rule, the rural floor for this FY 2021 final rule is calculated without the wage data of hospitals that have reclassified as rural under § 412.103. Lastly, for FY 2020, we placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 (84 FR 42336 through 42338). In light of the OMB updates described in section III.B.2. of the preamble of this final rule, for FY 2021, we are again capping any decreases in the wage index at 5 percent so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020.

As we discussed in the in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42638 through 42639), we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. Specifically, we established a 2-step methodology, under which we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, including our policy to remove the wage data of urban hospitals that have reclassified as rural under § 412.103 from the calculation of ''the wage index for rural areas in the State in which the county is located'' in applying the provisions of section 1886(d)(8)(C)(iii) of the Act, and the rural floor, including our policy to calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under § 412.103, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index and our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year. In this section, we refer to these two policies as the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases.

In light of the changes to the wage index and other wage index policies for FY 2021 discussed previously, which directly affect the GAF, we continue to compute a budget neutrality factor for changes in the GAFs in two steps. We discuss our 2-step calculation of the GAF budget neutrality factors for FY 2021 as follows.

To determine the GAF budget neutrality factors for FY 2021, we first compared estimated aggregate capital Federal rate payments based on the FY 2020 MS–DRG classifications and relative weights and the FY 2020 GAFs to estimated aggregate capital Federal rate payments based on the FY 2020 MS–DRG classifications and relative weights and the FY 2021 GAFs without incorporating the effects on the GAFs of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0021 for FY 2021. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2021 GAFs with and without incorporating the effects on the GAFs of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. For this calculation, estimated aggregate capital Federal rate payments were calculated using the FY 2021 MS–DRG classifications and relative weights, and the FY 2021 GAFs (both with and without incorporating the effects on the GAF of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases). (We note, for this calculation the GAFs included the out-migration and Frontier state adjustments.) To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases on the FY 2021 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9963. Therefore, to achieve budget neutrality for the changes in the GAFs, based on the calculations described previously, we are applying an incremental budget neutrality adjustment factor of 0.9984 (1.0021 x 0.9963) for FY 2021 to the previous cumulative FY 2020 adjustment factor.

We also compared estimated aggregate capital Federal rate payments based on the FY 2020 MS–DRG classifications and relative weights and the FY 2021 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the FY 2021 MS–DRG classifications and relative weights and the FY 2021 GAFs without the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. The incremental adjustment factor for DRG classifications and changes in relative weights is 0.9988. The incremental adjustment factors for MS–DRG classifications and changes in relative weights (0.9988) and for changes in the GAFs through FY 2021 (0.9984) is 0.9971 (0.9988 x 0.9984). We note that all the values are calculated with unrounded numbers.

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification and the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases described previously) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification or the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases described previously have on the other payment parameters, such as the payments for DSH or IME.

The incremental GAF/DRG adjustment factor of 0.9971 (the product of the incremental GAF budget neutrality adjustment factor of 0.9984 and the incremental DRG budget neutrality adjustment factor of 0.9988) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. As noted previously, it also incorporates the effects on the GAFs of FY 2021 geographic reclassification decisions made by the MGCRB compared to FY 2020 decisions and the lowest quartile hospital wage index adjustment, and the 5-percent cap on wage index decreases described earlier. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2021

For FY 2020, we established a capital Federal rate of $462.33 (84 FR 42640, as corrected in 84 FR 53613). We are establishing an update of 1.1 percent in determining the FY 2021 capital Federal rate for all hospitals. As a result of this update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $466.22 for FY 2021. The national capital Federal rate for FY 2021 was calculated as follows:

- The FY 2021 update factor is 1.011; that is, the update is 1.1 percent.
- The FY 2021 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9971.
- The FY 2021 outlier adjustment factor is 0.9466.

We are providing the following chart that shows how each of the factors and adjustments for FY 2021 affects the computation of the FY 2021 national capital Federal rate in comparison to the FY 2020 national capital Federal rate. The FY 2021 update factor has the effect of increasing the capital Federal rate by 1.1 percent compared to the FY 2020 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.29 percent. The FY 2021 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.03 percent compared to the FY 2020 capital Federal rate. The combined effect of all the changes would increase the national capital Federal rate by approximately 0.84 percent, compared to the FY 2020 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2020 CAPITAL FEDERAL RATE AND THE FY 2021 CAPITAL FEDERAL RATE

	FY 2020	FY 2021	Change	Percent Change
Update Factor[1]	1.0150	1.0110	1.0110	1.10
GAF/DRG Adjustment Factor[1]	0.9948	0.9971	0.9971	-0.29
Outlier Adjustment Factor[2]	0.9463	0.9466	1.0003	0.03
Capital Federal Rate	$462.33	$466.22	1.0084	0.84[3]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2020 to FY 2021 resulting from the application of the 0.9971 GAF/DRG budget neutrality adjustment factor for FY 2021 is a net change of 0.9971 (or –0.29 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2021 outlier adjustment factor is 0.9466/0.9463 or 1.0003 (or 0.03 percent).

[3] Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2021

For purposes of calculating payments for each discharge during FY 2021, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier threshold for FY 2021 is in section II.A. of this Addendum. For FY 2021, a case will qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.j. of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the fixed-loss amount of $29,051.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2021 IPPS/LTCH PPS final rule, we use the IPPS operating and capital market baskets that reflect a 2014 base year. For a complete discussion of the development of these market baskets, we refer readers to section IV. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38170).

2. Forecast of the CIPI for FY 2021

Based on IHS Global Inc.'s second quarter 2020 forecast, for this FY 2021 IPPS/LTCH PPS final rule, we are forecasting the 2014-based CIPI to increase 1.1 percent in FY 2021. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 1.7 percent increase in other capital expense prices in FY 2021, partially offset by a projected 1.7 percent decline in vintage-weighted interest expense prices in FY 2021. The weighted average of these three factors produces the forecasted 1.1 percent increase for the 2014-based CIPI in FY 2021. As proposed, we are using the more recent data available for this final rule to determine the FY 2021 increase in the 2014-based CIPI for the final rule.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2021

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of

increase limits established under § 413.40 of the regulations.)

For the FY 2021 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2019 forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2021 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, we stated in the proposed rule that the FY 2021 rate-of-increase percentage that would be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals would be 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we proposed that if more recent data became available for the final rule, we would use them, as appropriate, to calculate the IPPS operating market basket update for FY 2021. For this FY 2021 IPPS/LTCH PPS final rule, based on IGI's 2020 second quarter forecast, the 2014-based IPPS operating market basket update for FY 2021 is 2.4 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the FY 2021 rate-of-increase percentage that will be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.4 percent, in accordance with the applicable regulations at 42 CFR 413.40.

IRFs and rehabilitation distinct part units, IPFs and psychiatric distinct part units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this final rule and section V. of the Addendum to this final rule for the updated changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2021. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

We did not receive public comments related to the rate-of-increase percentage used to determine the target amounts for excluded hospitals for FY 2021. Therefore, for the reasons set forth in this final rule and in the FY 2021 IPPS/LTCH PPS proposed rule, we are finalizing as proposed, without modification, our policy for updating the target amounts for the excluded hospitals discussed in this section.

V. Changes to the Payment Rates for the LTCH PPS for FY 2021

A. LTCH PPS Standard Federal Payment Rate for FY 2021

1. Overview

In section VII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2021.

Under § 412.523(c)(3) of the regulations, for LTCH PPS FYs 2012 through 2020, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II), and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xv)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.C.2 of the preamble of this final rule.

This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.C.2. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the FY 2021 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2021, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2021, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2021 LTCH PPS standard Federal payment rate, as we proposed, we are applying a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data, labor-related share, and geographic labor-market area designations, and the 5-percent cap on any decrease in a LTCH's wage index transition policy) as discussed in section V.B.6 of this Addendum to this final rule. In addition, as we proposed, we applied the permanent budget neutrality adjustment factor (applied to LTCH PPS standard Federal payment rate cases only) for the cost of the elimination of the 25-percent threshold policy for FY 2021 (discussed in section VII.D. of the preamble of this final rule).

In this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 2.3 percent. Accordingly, as reflected in § 412.523(c)(3)(xvii), we are applying a factor of 1.023 to the FY 2020 LTCH PPS standard Federal payment rate of $42,677.64 to determine the FY 2021 LTCH PPS standard Federal payment rate. Also, as reflected in § 412.523(c)(3)(xvii), applied in conjunction with the provisions of § 412.523(c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2021 as required under the LTCH QRP. Therefore, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 0.3 percent (that is, an update factor of 1.003) for FY 2021 for LTCHs that fail to submit the required quality reporting data for FY 2021 as required under the LTCH QRP. Additionally, as discussed in VII.C. of the preamble of this final rule, we are applying a permanent budget neutrality adjustment factor of 0.991249 to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2021 and subsequent years after removing the temporary budget neutrality adjustment factor of 0.990737 that was applied to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2020 (or a factor of 1.000517, calculated as $1/0.990737 \times 0.991249$). Consistent with § 412.523(d)(4), we also are applying an area wage level budget neutrality factor to the FY 2021 LTCH PPS standard Federal payment rate of 1.0016837, based on the best available data at this time, to ensure that any changes to the general updates to the area wage level adjustment (that is, the annual update of the wage index, including any changes to the geographic labor-market area designations and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $43,755.34 (calculated as $\$42,677.64 \times 1.000517 \times 1.023 \times 1.0016837$ for FY 2021 (calculations performed on unrounded numbers). For LTCHs that fail to submit quality reporting data for FY 2021, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $42,899.90 (calculated as $\$42,677.64 \times 1.000517 \times 1.003 \times 1.0016837$) (calculations performed on unrounded numbers) for FY 2021.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2021

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to

reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The FY 2021 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2020, through September 30, 2021, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. (As noted elsewhere in this final rule, we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census.

However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42642), we adopted our current policy, that is, the continued use of the CBSA-based labor market area delineations as established in OMB Bulletin 17–01 and adopted in the FY 2019 IPPS/LTCH PPS final rule.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data. A copy of the September 14, 2018 OMB Bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.* (We note, on March 6, 2020 OMB issued OMB Bulletin 20–01 (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*), and as discussed later in this section of this rule was not issued in time for development of the proposed rule.) While OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations, including some new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32920 through 32921), we proposed to adopt the revised delineations announced in OMB Bulletin No. 18–04 effective for FY 2021 under the LTCH PPS. We did not receive any public comments on this proposal. Therefore, in this final rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are adopting the revised delineations announced in OMB Bulletin No. 18–04 effective for FY 2021 under the LTCH PPS, as we proposed, without modification. As noted previously, the March 6, 2020 OMB Bulletin 20–01 was not issued in time for development of the proposed rule. The minor updates included in OMB Bulletin 20–01 do not alter the urban or rural status of any county, and do not impact our updates to the CBSA-based labor market area delineations discussed in this section of the rule. Our adoption of the revised delineations announced in OMB Bulletin No. 18–04 is consistent with the changes under the IPPS for FY 2021 as discussed in section III.A.2. of the preamble of this final rule. A summary of these changes is presented in the discussion that follows in this section. For complete details on the changes we refer readers to section III.A.2. of the preamble of this final rule.

a. Urban Counties That Will Become Rural Under the Revised OMB Delineations

Under the revised OMB labor market area delineations, 34 counties (and county equivalents) currently considered part of an urban CBSA will be considered to be located in a rural area beginning in FY 2021 under our adoption of the revisions to the OMB delineations based on OMB Bulletin No. 18–04. The chart in section III.A.2.ii. of the preamble of this final rule lists the 34 urban counties that will be rural under these revisions to the OMB delineations.

b. Rural Counties That Will Become Urban Under the Revised OMB Delineations

Under the revised labor market area delineations shows that a total of 47 counties (and county equivalents) located in rural areas that will be located in urban areas beginning in FY 2021 under our adoption of the revisions to the OMB delineations based on OMB Bulletin No. 18–04. The chart in section III.A.2.iii. of the preamble of this final rule lists the 47 rural counties that will be urban under these revised OMB delineations.

c. Urban Counties That Will Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, some urban counties will shift from one urban CBSA to another urban CBSA under our adoption of the revised delineations announced in OMB Bulletin No. 18–04. In other cases, the adoption of the revised delineations announced in OMB Bulletin No. 18–04 will involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) will experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties will remain the same. In other cases, only the name of the CBSA will be modified, and none of the currently assigned counties will be reassigned to a different urban CBSA. The chart in section III.A.2.iii. of the preamble of this final rule lists the CBSAs where only the name and/or CBSA number changed.

There are also counties that will shift between existing and new CBSAs, changing the constituent makeup of the CBSAs, under our adoption of the revisions to the OMB delineations based on OMB Bulletin No. 18–04. For example, some CBSAs will be split into multiple new CBSAs, or a CBSA will lose one or more counties to other urban CBSAs. The chart in section III.A.2.iv. of the preamble of this final rule lists the urban counties that will move from one urban CBSA to a new or modified CBSA under our after adoption of these revisions to the OMB delineations.

We believe these revisions to the CBSA-based labor market area delineations as established in OMB Bulletin 18–04 will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, as we proposed, we are adopting the revisions announced in OMB Bulletin No. 18–04 to the CBSA-based labor market area delineations under the LTCH PPS, effective October 1, 2020. Accordingly, the FY 2021 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website) reflect the revisions to the CBSA-based labor market area delineations previously described. We note that, as discussed in section III.A.2. of the preamble of this final rule, these revisions to the CBSA-based delineations also are being adopted under the IPPS.

As indicated previously, overall, we believe that our adoption of the revised delineations announced in OMB Bulletin No. 18–04 will result in LTCH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some LTCHs will experience decreases in their area wage index values as a result of adopting the revisions to the OMB delineations. We also realize that many LTCHs will have higher area wage index values under our adoption of these revisions to the OMB delineations. To mitigate the impact upon LTCHs, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. While we believe that using the new OMB delineations will create a more accurate payment adjustment for differences in area wage levels, as we discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32921), we also recognize that adopting such changes may cause some short-term instability in LTCH PPS payments. Therefore, we proposed a transition policy to help mitigate any significant negative impacts that LTCHs may experience due to our proposal to adopt the revised OMB delineations under the LTCH PPS. Consistent with past practice, we proposed that this transition would be implemented in a budget neutral manner. As discussed in section V.B.5. of the Addendum to this final rule, as we proposed, we are establishing a transition policy to help mitigate any significant negative impacts that LTCHs may experience due to our adoption of the revised OMB delineations under the LTCH PPS. Consistent with past practice, this transition will be implemented in a budget neutral manner, as discussed in section V.B.6. of the Addendum to this final rule.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) Then, effective for FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).)

As noted previously in section V.A. in this Addendum to this final rule, effective for FY 2021, as we proposed, we are rebasing and revising the 2013-based LTCH market basket to reflect a 2017 base year. In addition, as discussed in section VII.D.6. of the preamble of this final rule, as we proposed, we are establishing that the LTCH PPS labor-related share for FY 2021 is the sum of the FY 2021 relative importance of each labor-related cost category in the 2017-based LTCH market basket using the most recent available data. For more information on comments related to our proposed labor-related share as well as our responses to those comments, we refer readers to section VII.D.6. of the preamble of this final rule. Also as we proposed, consistent with our historical practice, we are using the most recent data available to determine the final FY 2021 labor-related share in this final rule.

Table E9 in section VII.D.6. of the preamble of this final rule shows the FY 2021 labor-related share using the 2017-based LTCH market basket and the FY 2020 labor-related share using the 2013-based LTCH market basket. The labor-related share for FY 2021 is the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related cost weight from the 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2021. Based on IHS Global Inc.'s second quarter 2020 forecast of the 2017-based LTCH market basket, the sum of the FY 2021 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 63.7 percent. The portion of Capital-Related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2013-based LTCH market basket. Since the FY 2021 relative importance for Capital-Related is 9.5 percent based on IHS Global Inc.'s second quarter 2020 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.5 percent to determine the labor-related share of Capital-Related for FY 2021 of 4.4 percent. Therefore, consistent with our proposal, we are establishing a total labor-related share for FY 2021 of 68.1 percent (the sum of 63.7 percent for the operating cost and 4.4 percent for the labor-related share of Capital-Related). The total difference between the FY 2021 labor-related share using the 2017-based LTCH market basket and the FY 2020 labor-related share using the 2013-based LTCH market basket is 1.8 percentage points (68.1 percent and 66.3 percent, respectively). As discussed in greater detail in section VII.D.6. of the preamble of this final rule, this difference is attributable to the revision to the base year cost weights, the revision to the starting point of the calculation of relative importance (base year) from 2013 to 2017, and the use of an updated IHS Global Inc. forecast and reflecting an additional year of inflation.

4. Wage Index for FY 2021 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42643), we calculated the FY 2020 LTCH PPS area wage index values using the same data used for the FY 2020 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2016), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2020 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area

wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2021 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we are continuing to employ our historical practice of using the same data we used to compute the FY 2021 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule, that is wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2017, because these data are the most recent complete data available.

In addition, as we proposed, we computed the FY 2021 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the labor market area delineations, including the updates, as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we proposed, we also continued to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values and as we proposed, for FY 2021 we continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2017 IPPS wage data that we used to determine the FY 2021 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the FY 2021 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website.

Based on the FY 2017 IPPS wage data that we used to determine the FY 2021 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2021. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Transition Wage Index for LTCHs Negatively Impacted

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32922), overall, we believe that our proposal to adopt the revised OMB delineations announced in Bulletin No. 18–04 for FY 2021 would result in LTCH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some LTCHs would experience decreases in their area wage index values as a result of our proposal. We also realize that some LTCHs would have higher area wage index values under our proposal.

To mitigate the potential impacts of policies on LTCHs, as we explained in the FY 2021 IPPS/LTCH PPS proposed final rule, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget neutral transition policies to help mitigate negative impacts on LTCHs following the adoption of the new CBSA delineations based on the 2010 decennial census data in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50185). Specifically, we implemented a 1-year 50/50 blended wage index for any LTCHs that experienced a decrease in wage index values due to our adoption of the revised delineations. This required calculating and comparing two wage indexes for each LTCH since that blended wage index was computed as the sum of 50 percent of the FY 2015 LTCH PPS wage index values under the FY 2014 CBSA delineations and 50 percent of the FY 2015 LTCH PPS wage index values under the FY 2015 new OMB delineations. While we believed that using the new OMB delineations would ultimately create a more accurate payment adjustment for differences in area wage levels, we also recognized that adopting such changes may cause some short-term instability in LTCH PPS payments. Similar instability may result from the wage policies herein, in particular for LTCHs that would be negatively impacted by the adoption of the updates to the OMB delineations. For example, LTCH's currently located in CBSA 35614 (New York–Jersey City–White Plains, NY–NJ) that would be located in new CBSA 35154 (New Brunswick–Lakewood, NJ) under the changes to the CBSA-based labor market area delineations would experience a nearly 17 percent decrease in the wage index as a result of the change. (85 FR 32922)

Consistent with our past practice of implementing transition policies to help mitigate negative impacts on hospitals following the adoption of the new CBSA delineations, we proposed that if we adopt the revised delineations announced in OMB Bulletin 18–04, it would be appropriate to implement a transition policy since, as mentioned previously, some of these revisions are material, and may negatively impact payments to LTCHs. Similar to the proposed policy under the IPPS for the adoption of the revised delineations announced in OMB Bulletin 18–04 discussed in section III.A.2. of the preamble to the proposed rule, we believe applying a 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index from the prior fiscal year would be an appropriate transition for FY 2021 for the revised OMB delineations as it provides transparency and predictability in payment levels from FY 2020 to the upcoming FY 2021. The FY 2021 5-percent cap on wage index decreases would be applied to all LTCHs that have any decrease in their wage indexes, regardless of the circumstance causing the decline. Given the significant portion of Medicare LTCH PPS payments that are adjusted by the wage index and how relatively few LTCHs generally see wage index declines in excess of 5 percent, LTCHs may have difficulty adapting to changes in the wage index of this magnitude all at once. For these reasons, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32922), under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we proposed to apply a 5-percent cap on any decrease in a LTCH's wage index from the LTCH's wage index from the prior fiscal year such that that an LTCH's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. This transition would allow the effects of our adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in an LTCH's wage index would be capped at 5 percent in FY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (FY 2022)). Because we believe that using the new OMB delineations would ultimately create a more accurate payment adjustment for differences in area wage levels we did not propose to include a cap on the overall increase in an LTCH's wage index value.

Furthermore, consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we proposed that this 5 percent cap on the decrease on an LTCH's wage index would not result in any change in estimated aggregate LTCH PPS payments by including the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed in section V.B.6. of the Addendum to the proposed rule.

Comment: A commenter expressed support for the proposed 5-percent cap on wage index decreases. However, the commenter encouraged CMS to also apply a 5-percent cap on wage index increases and to implement that policy in a budget neutral manner.

Another commenter noted that the FY 2021 LTCH PPS Impact File that accompanied the proposed rule did not include the proposed wage indexes for LTCHs after the 5-percent cap on wage index decreases was applied. The commenter recommended that in this final rule, we ensure that the wage index value for every LTCH with a final wage index value that would decreases by more than 5

percent show the application of the cap, as we proposed.

Response: We appreciate the suggestion that the cap on wage index changes of more than 5 percent should also be applied to increases in the wage index. However, as we discussed in the proposed rule, the purpose of the proposed transition policy, as well as those we have implemented in the past, is to help mitigate the significant negative impacts of certain wage index changes. We believe that using the new OMB delineations will ultimately create a more accurate payment adjustment for differences in area wage levels and thus we do not think it would be appropriate to apply the 5 percent cap on wage index increases as well.

After consideration of the public comments we received, for the reasons discussed above, we are finalizing without modification our proposal to apply a 5-percent cap on any decrease in a LTCH's wage index from the LTCH's wage index from the prior fiscal year such that that an LTCH's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020. In addition we are finalizing without modification our proposal adopt the 5 percent cap on the decrease on an LTCH's wage index in a budget neutral manner by including the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, which is discussed in section V.B.6. of the Addendum to this final rule.

In response to the comment that the FY 2021 LTCH PPS Impact File that accompanied the proposed rule did not include the LTCH wage indexes after the 5-percent cap on wage index decreases was applied, we have included in the FY 2021 LTCH PPS Impact File that accompanies this final rule the LTCH wage indexes without the 5-percent cap on wage index decreases applied, as well as the final LTCH wage indexes for FY 2021 (which do have the 5-percent cap on wage index decreases applied).

6. Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2021, in accordance with § 412.523(d)(4), as we proposed, we applied an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed previously, the 5 percent cap on the decrease on an LTCH's wage index will be implemented in a budget neutral manner by including the application of that policy in the area wage level a budget neutrality factor that is applied to the standard Federal payment rate.

Specifically, as we proposed, we determined an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2021 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2020 wage index values, the FY 2020 labor-related share of 66.3 percent, and the FY 2020 labor market area designations.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2021 wage index values based on updated hospital wage data, including the 5 percent cap on the decrease on an LTCH's wage index, the FY 2021 labor-related share of 68.1 percent, and the FY 2021 labor market area designations. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4.a. of this Addendum to this final rule; the transitional 5 percent cap on the decrease on an LTCH's wage index is discussed in section V.B.5. of this Addendum to this final rule, the labor-related share is discussed in section V.B.3. of this Addendum to this final rule, and changes to the geographic labor-market area designations are discussed in section V.B.2. of this Addendum to this final rule.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2020 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2021 general updates to the area wage level adjustment (calculated in Step 2) to determine the budget neutrality factor for general updates to the area wage level adjustment for FY 2021 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the FY 2021 general updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2021 LTCH PPS standard Federal payment rate after the application of the FY 2021 annual update.

We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2021 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. In addition, we note that the estimated LTCH PPS standard Federal payment rate used in the calculations in Steps 1 through 4 include the permanent one-time budget neutrality adjustment factor for the estimated cost of eliminating the 25-percent threshold policy in FY 2021 and subsequent years (discussed in section VII.D. of the preamble of this final rule).

For this final rule, using the steps in the methodology previously described, we determined a FY 2021 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0016837. Accordingly, in section V.A. of the Addendum to this final rule, to determine the FY 2021 LTCH PPS standard Federal payment rate, we applied the area wage level adjustment budget neutrality factor of 1.0016837, in accordance with § 412.523(d)(4).

C. LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2018 (82 FR 38539 through 38540).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32923 through 32924), for FY 2021, under the broad authority conferred upon the

Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we proposed to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2016 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2018 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2018 COLA factors, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540).)

We did not receive any public comments on our proposal. Therefore, we are adopting our proposal, without modification. Consistent with our historical practice, we are establishing that the COLA factors shown in the following table will be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2021

Area	FY 2021
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement at § 412.522(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, as we proposed, we used the most recent data available to determine the LTCH total CCR ceiling for FY 2021 in this final rule. Specifically, in this final rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2020 update of the Provider Specific File (PSF), which is the most recent data available, we are establishing an LTCH total CCR ceiling of 1.24 under the LTCH PPS for FY 2021 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification.

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this final rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2020 update of the PSF, as we proposed, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2020, through September 30, 2021, in Table 8C listed in section VI. of the Addendum to this final rule (and available via the internet on the CMS website). Consistent with our historical practice, as we also proposed, we used more recent data to determine the LTCH PPS statewide average total CCRs for FY 2021 in this final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in these areas as of March 2020. Therefore, consistent with our existing methodology, as we proposed, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 0.949. Because this is much higher than the statewide urban average (0.459) and furthermore implies costs are nearly equal to charges, as with Connecticut, we used the national average total CCR for rural hospitals for hospitals located in rural Massachusetts. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification.

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Changes to High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2021

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results

in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32925), we proposed to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 using the best available data that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the proposed rule).

Specifically, based on the most recent complete LTCH data available at that time (that is, LTCH claims data from the December 2019 update of the FY 2019 MedPAR file and CCRs from the December 2019 update of the PSF), we determined a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 of $30,515 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2021 payments for such cases. We also proposed to continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,515).

Consistent with our historical practice of using the best data available, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 in the final rule, we proposed to use the most recent available LTCH claims data and CCR data.

Comment: Some commenters stated that CMS continues to propose increases to the LTCH PPS standard Federal payment rate high cost outlier threshold. These commenters noted that an increase in the fixed-loss amount will result in reductions of the number of cases that qualify as high-cost outliers. One commenter added that the proposed increase in the fixed-loss amount would require LTCHs to absorb even more costs during a time when they are already struggling with high COVID related expenses. Commenters suggested that CMS leave the fixed-loss threshold at the FY 2020 amount of $26,778.

Another commenter stated that CMS did not explain the proposed increase in the fixed-loss amount from FY 2020 of $26,778 to the FY 2021 proposed amount of $30,515. The commenter continued by indicating that, based on historical experience, the final fixed-loss amount would likely decrease from the proposed amount but expressed concern that the final fixed-loss amount may still reflect a significant increase. This commenter also stated that CMS did not explain how the charge inflation factor, which is integral to the determination of the fixed-loss amount, is calculated, and requested that CMS provide more information on how the fixed-loss amount for LTCH PPS standard Federal payment rate cases is calculated and the reasons for any significant changes.

Response: We thank the commenters for their input and suggestions. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We therefore are required by existing regulations to determine a fixed-loss amount for the fiscal year, based on the most recently available data. We project that if the fixed-loss amount was kept at the FY 2020 amount of $26,778, outlier payments would be equal to 8.044 percent of total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, as described below, an increase in the fixed-loss amount for FY 2021 is necessary to maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

As stated in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32963), consistent with past practice, in calculating estimated high cost outlier payments for that proposed rule, we increased estimated costs by an inflation factor of 5.4 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2021. Based on the data available for this final rule, in calculating estimated high cost outlier payments for this final rule, we increased estimated costs by an inflation factor of 4.3 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2021. The charge inflation factor is the average value resultant from eight quarterly market basket updates. To calculate a two-year charge inflation factor for FY 2021 for this final rule, consistent with historical practice, we divided the average of the four quarter market basket values for FY 2021 (1.093) by the average of the four quarter market basket values for FY 2019 (1.047), which results in a two-year charge inflation factor for FY 2021 of 1.043 (calculation performed using unrounded numbers). Therefore, consistent with past practice, in determining a FY 2021 fixed-loss amount that would result in estimated outlier payments for FY 2021 being projected to be equal to 7.975 percent of projected total FY 2021 LTCH PPS payments for LTCH PPS standard Federal payment rate cases, we inflated the charges on the MedPAR claims by 2 years, from FY 2019 to FY 2021, using the two-year charge inflation factor of 1.043.

After consideration of public comments we are finalizing our proposals without modification. In addition, consistent with our historical practice of using the best data available, as we proposed, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 in this final rule, we used the most recent available LTCH claims data and CCR data.

For this FY 2021 IPPS/LTCH PPS final rule, we are continuing to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 using the best available data that will maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in this final rule). Specifically, based on the most recent complete LTCH data available at this time (that is, LTCH claims data from the March 2020 update of the FY 2019 MedPAR file and CCRs from the March 2020 update of the PSF), we determined a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 of $27,195 that will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2021 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount of $27,195 for LTCH PPS standard Federal payment rate cases for FY 2021. Under this policy, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,195).

We note, the fixed-loss amount for FY 2021 for LTCH PPS standard Federal payment rate cases we are establishing in this final rule based on the most recent LTCH claims data from the MedPAR file and the latest CCRs from the PSF, result in a fixed-loss amount for such cases that is lower than the proposed fixed-loss amount. This change is largely attributable to updates to CCRs from the December 2019 update of the PSF to the March 2020 update of the PSF. As previously discussed, the increase in the fixed-loss amount from FY 2020 of $26,778 to the FY 2021 amount of $27,195 is necessary to maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FY 2019

and FY 2020, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2018 and FY 2019 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2020, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2020 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2020. In particular, in FY 2020, we established the fixed-loss amount for site neutral payment rate cases as the FY 2020 IPPS fixed-loss amount of $26,552 (as corrected at 84 FR 49845).

As noted earlier, because not all claims in the data used for this FY 2021 IPPS/LTCH PPS final rule were subject to the unblended site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2020 when developing a fixed-loss amount for site neutral payment rate cases for FY 2021. Our actuaries continue to project that site neutral payment rate cases in FY 2021 will continue to mirror an IPPS case paid under the same MS–DRG. That is, our actuaries continue to project that the costs and resource use for FY 2021 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the most recent FY 2019 LTCH claims data used in the development of this FY 2021 IPPS/LTCH PPS final rule, approximately 75 percent of LTCH cases were paid the LTCH PPS standard Federal payment rate and approximately 25 percent of LTCH cases were paid the site neutral payment rate for discharges occurring in FY 2019.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2021 is the IPPS fixed-loss amount for FY 2021. Therefore, consistent with past practice, in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32926), we proposed that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $30,006. Accordingly, for FY 2021, we proposed to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $30,006).

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposals as described above, without modification. Therefore, for FY 2021, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $29,051, which is the same FY 2021 IPPS fixed-loss amount discussed in section II.A.4.g.(1). of the Addendum to this final rule. Accordingly, under this policy, for FY 2021, we will calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $29,051).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2021 would not result in any increase in estimated aggregate FY 2021 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2021, in general, we proposed to continue this policy.

As explained in the proposed rule, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2021 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2021 would not result in any increase in estimated aggregate FY 2021 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), as we explained in the proposed rule, it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2021. In order to achieve this, for FY 2021, we proposed to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

Comment: Some commenters, as they have done since the inception of the dual rate payment system that created the site neutral payment rate, objected to the proposed site neutral payment rate HCO budget neutrality adjustment, claiming that it would result in savings to the Medicare program instead of being budget neutral. The commenters' primary objection continued to be based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (for example, a 5.1 percent adjustment on the operating IPPS standardized amount), an ''additional'' budget neutrality factor is not necessary and is, in fact, duplicative. Based on their belief that the proposed site neutral payment rate HCO budget neutrality adjustment is duplicative, some commenters recommended that if CMS continues with the application of that budget neutrality adjustment, the calculation of the IPPS comparable per diem amount should be revised to use the IPPS operating standardized amount prior to the application of the IPPS HCO budget neutrality adjustment.

Response: We continue to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO

payments is unnecessary or duplicative. We have stated such disagreement during each previous rulemaking cycle. We refer readers to 84 FR 42648 through 42649, 83 FR 41737 through 41738, 82 FR 38545 through 38546, 81 FR 57308 through 57309, and 80 FR 49621 through 49622 for more information on our responses to these comments.

After consideration of public comments, for the reasons discussed above, we are adopting our proposed site neutral payment rate HCO budget neutrality adjustment as final without modification. Specifically, for FY 2021, as we proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment will not apply to the HCO portion of the site neutral payment rate amount.

E. Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32927), based on the data available at that time, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 75.90 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that, if more recent data became available, we would use that data to determine this factor in this final rule.

We did not receive any public comments in response to our proposal, and we are adopting it as final. However, as we proposed we are determine the factor in this final rule using more recent data. For FY 2021, as discussed in greater detail in section IV.G.3. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 72.86 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2021. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 54.65 percent (the product of 75 percent and 72.86 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2021, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 79.65 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 54.65 percent = 79.65 percent).

Therefore, for FY 2021, consistent with our proposal, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 will include an applicable operating Medicare DSH payment amount that is equal to 79.65 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2021

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2021 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this final rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the final FY 2021 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2021 of $43,755.34, as discussed in section V.A. of the Addendum to this final rule. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2021 in the following example:

Example: During FY 2021, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a FY 2021 LTCH PPS wage index value of 1.0442 (obtained from Table 12A listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2021 of 0.9446 (obtained from Table 11 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website). The LTCH submitted quality reporting data for FY 2021 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2021, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2021 LTCH PPS standard Federal payment rate ($43,755.34) by the labor-related share (0.681 percent) and the

wage index value (1.0442). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (0.319 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9446) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2021 ($42,575.37). The table illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$43,755.34
Labor-Related Share	x 0.681
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $29,797.39
Wage Index (CBSA 16984)	x 1.0442
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $31,114.43
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($43,755.34 x 0.319)	+ $13,957.95
Adjusted LTCH PPS Standard Federal Payment Amount	= $45,072.38
MS-LTC-DRG 189 Relative Weight	x 0.9446
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $42,575.37

VI. Tables Referenced in This Final Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2020, for the FY 2021 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42650 through 42651).

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital-level data for the FY 2021 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As was the cases for the FY 2020 IPPS/LTCH PPS proposed and final rules, we are no longer including Table 15, which had typically included the fiscal year readmissions payment adjustment factors because hospitals have not yet had the opportunity to review and correct the data before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2021, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2021 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2020. We expect Table 15 will be posted on the CMS website in the fall of 2020.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final rule are generally available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, ''FY 2021 IPPS Final Rule Home Page'' or ''Acute Inpatient-Files- for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2021
Table 3.—Wage Index Table by CBSA—FY 2021
Table 4A.—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2021
Table 4B.—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2021
Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2021
Table 6A.—New Diagnosis Codes—FY 2021
Table 6B.—New Procedure Codes—FY 2021
Table 6C.—Invalid Diagnosis Codes—FY 2021
Table 6E.—Revised Diagnosis Code Titles—FY 2021
Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List-FY 2021
Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2021
Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2021
Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021
Table 6I.—Complete MCC List—FY 2021
Table 6I.1.—Additions to the MCC List—FY 2021
Table 6I.2.—Deletions to the MCC List—FY 2021
Table 6J.—Complete CC List—FY 2021
Table 6J.1.—Additions to the CC List—FY 2021
Table 6J.2.—Deletions to the CC List—FY 2021
Table 6K.—Complete List of CC Exclusions—FY 2021
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for MS–DRG Changes—FY 2021 (Table 6P contains multiple tables, 6P.1a. through 6P.4a., that include the ICD–10–CM and ICD–10–PCS code lists relating to specific MS–DRG changes. These tables are referred to throughout section II.D. of the preamble of this final rule.)
Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update—March 2020 GROUPER Version 37 MS–DRGs
Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update—March 2020 GROUPER Version 38 MS–DRGs
Table 8A.—FY 2021 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—FY 2021 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 16A.—Updated Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2021
Table 18.—FY 2021 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2021 final rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1735–F:

Table 8C.—FY 2021 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2020 through September 30, 2021
Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2020 through September 30, 2021

Table 12B.— LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2020 through September 30, 2021

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TABLE 1A.— NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2021

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.4 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.6 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.8 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = 0 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,071.49	$1,889.70	$3,999.92	$1,856.48	$4,047.63	$1,878.63	$3,976.06	$1,845.41

TABLE 1B.— NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2021

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.4 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.6 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.8 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = 0 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,695.94	$2,265.25	$3,630.97	$2,225.43	$3,674.28	$2,251.98	$3,609.31	$2,212.16

TABLE 1C.— ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2021

	Rates if Wage Index is Greater Than 1		Rates if Wage Index is Less Than or Equal to 1	
Standardized Amount	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,695.94	$2,265.25

[1] For FY 2021, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.— CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2021

	Rate
National	466.22

TABLE 1E.— LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2021

	Full Update (2.3 Percent)	Reduced Update* (0.3 Percent)
Standard Federal Rate	$43,755.34	$42,899.90

* For LTCHs that fail to submit quality reporting data for FY 2021 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

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Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS.

Also as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule, such as the updates to the IPPS and LTCH PPS rates, and the policies and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

For example, without additional payments for new medical technologies that meet the criteria for approval for new technology add-on payments, Medicare beneficiaries may not have appropriate access to these new technologies. We discuss the technologies for which we received applications for add-on payments for new medical technologies for FY 2021 in sections II.G.5. and 6. of the preamble to this final rule. As discussed in section II.G.6. of the preamble of this final rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a Qualified Infectious Disease Product (QIDP) designation or are part of the Breakthrough Device program will be considered new and not substantially similar to an existing technology and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still meet the cost criterion.

We expect that the policies in this final rule would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the changes for FY 2021 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, would result in an estimated $3.5 billion increase in FY 2021 payments, primarily driven by a combined $3.0 billion increase in FY 2021 operating payments and uncompensated care payments, and a net increase of $506 million resulting from estimated changes in FY 2021 capital payments and new technology add-on payments. These changes are relative to payments made in FY 2020. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by approximately 40 million in FY 2021 relative to FY 2020, primarily due to the end of the statutory transition period for site neutral payment rate cases.

Our operating impact estimate includes the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this final rule. In addition, our operating payment impact estimate includes the 2.4 percent hospital update to the standardized amount (which includes the estimated 2.4 percent market basket update and the 0.0 percentage point for the multifactor productivity (MFP) adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this final rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2021, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case-mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 27 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of July 2020, there were 3,201 IPPS acute care hospitals included in our analysis. This represents approximately 54 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are

approximately 1,414 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, 1 extended neoplastic disease care hospital, and 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2021 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2020, there were 95 children's hospitals, 11 cancer hospitals, 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 15 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 302 rehabilitation hospitals and 816 rehabilitation units, and approximately 363 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 547 psychiatric hospitals and 1,003 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the 1 extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2021 percentage increase in the 2014-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's second quarter 2020 forecast of the 2014-based IPPS market basket increase, we are estimating the FY 2021 update to be 2.4 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section IV.B. of the preamble of this final rule. We used the most recent data available for this final rule to calculate the IPPS operating market basket update for FY 2021. Children's hospitals, the 11 cancer hospitals, the 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the 1 extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2021 for operating costs of acute care hospitals. The FY 2021 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2021 operating payments would increase by 2.5 percent, compared to FY 2020. In addition to the applicable percentage increase, this amount reflects the +0.5 percentage point permanent adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available claims data to enable us to estimate the impacts on payments per case of certain changes in this final rule. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2019 MedPAR file and the most current Provider-Specific File (PSF) that are used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2019 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2021 are discussed in section I.I. of this Appendix.

We discuss the following changes:

- The effects of the application of the applicable percentage increase of 2.4 percent (that is, a 2.4 percent market basket update with a 0.0 percentage point adjustment for the multifactor productivity adjustment), and a 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the applicable percentage increase (including the market basket update and the multifactor productivity adjustment) to the hospital-specific rates.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2017, compared to the FY 2016 wage data, to calculate the FY 2021 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2021.
- The effects of the rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2021. This provision is not budget neutral.
- The total estimated change in payments based on the FY 2021 policies relative to payments based on FY 2020 policies,

including estimated changes in outlier payments, the revised labor market area delineations in OMB Bulletin No. 18–04 and the transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year.

To illustrate the impact of the FY 2021 changes, our analysis begins with a FY 2020 baseline simulation model using: The FY 2020 applicable percentage increase of 2.6 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2020 MS–DRG GROUPER (Version 37); the FY 2020 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2020 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, as discussed in section IV.B.1. of the preamble of this final rule, for FY 2021, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.8 percent. At the time this impact was prepared, 37 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2021 using a reduced update for these hospitals.

For FY 2021, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, as discussed in section IV.B.1. of the preamble of this final rule, for FY 2021, hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.6 percent. At the time this impact analysis was prepared, 153 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2021 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a applicable percentage increase of 0 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 30 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2021 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the percent change in payments per case from FY 2020 to FY 2021. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2021 using an applicable percentage increase of 2.4 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.4 percent with a 0.0 percentage point reduction for the multifactor productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive an update of 1.8 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive an update of 0.6 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a update of 0.0 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 2.4 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2020 to FY 2021 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2020 that are no longer reclassified in FY 2021. Conversely, payments may increase for hospitals not reclassified in FY 2020 that are reclassified in FY 2021.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2021. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,201 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: Urban and rural. There are 2,462 hospitals located in urban areas and 739 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2021 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,049, and 1,152, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,037 nonteaching hospitals in our analysis, 907 teaching hospitals with fewer than 100 residents, and 257 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, MDHs and RRCs). There were 483 RRCs, 304 SCHs, 145 MDHs, 149 hospitals that are both SCHs and RRCs, and 25 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total inpatient days. These data were taken from the FY 2018 or FY 2017 Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2021 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

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TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2021

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2021 Changes (7)[8]
All Hospitals	3,201	2.8	0.0	0.0	0.0	0.0	0.1	2.5
By Geographic Location:								
Urban hospitals	2,462	2.9	0.0	0.0	-0.1	0.0	0.1	2.5
Rural hospitals	739	2.6	-0.3	0.1	1.1	-0.2	0.1	2.2
Bed Size (Urban):								
0-99 beds	635	2.8	-0.5	-0.1	-0.7	0.1	0.3	2.0
100-199 beds	756	2.9	-0.1	0.0	-0.1	0.1	0.2	2.4
200-299 beds	426	2.9	-0.1	0.0	0.3	0.1	0.1	2.4
300-499 beds	422	2.9	0.0	-0.1	0.0	0.0	0.2	2.4
500 or more beds	223	2.8	0.2	0.1	-0.3	-0.1	0.0	2.7
Bed Size (Rural):								
0-49 beds	312	2.5	-0.6	0.0	0.2	-0.1	0.2	2.0
50-99 beds	254	2.5	-0.3	0.0	0.8	-0.1	0.1	2.1
100-149 beds	95	2.6	-0.3	0.2	1.4	-0.2	0.0	2.2
150-199 beds	39	2.7	-0.2	0.3	1.3	-0.1	0.2	2.3
200 or more beds	39	2.7	-0.1	0.1	1.8	-0.2	0.0	2.2
Urban by Region:								
New England	112	2.9	0.1	-0.8	1.8	2.3	0.1	2.7
Middle Atlantic	305	2.9	0.0	0.6	0.3	-0.4	0.2	2.8
East North Central	381	2.9	0.0	0.1	-0.3	-0.3	0.0	2.5
West North Central	160	2.8	0.0	-0.5	-0.8	-0.3	0.6	2.0

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2021 Changes (7)[8]
South Atlantic	402	2.9	0.0	0.1	-0.5	-0.3	0.0	2.5
East South Central	144	2.9	0.0	0.0	-0.4	-0.3	0.0	2.4
West South Central	364	2.8	0.0	0.1	-0.6	-0.3	0.0	2.5
Mountain	172	2.8	-0.1	-0.5	-0.2	0.1	0.3	1.8
Pacific	372	2.8	0.1	-0.1	0.3	0.7	0.1	2.7
Puerto Rico	50	2.9	0.1	-0.9	-1.0	0.2	0.1	1.8
Rural by Region:								
New England	19	2.7	-0.1	0.2	0.4	-0.2	0.0	2.4
Middle Atlantic	50	2.6	-0.2	0.3	1.2	-0.2	0.0	2.2
East North Central	114	2.5	-0.3	0.1	0.9	-0.1	0.0	2.2
West North Central	89	2.4	-0.4	0.0	-0.3	0.1	0.3	2.0
South Atlantic	114	2.7	-0.2	0.4	1.6	-0.2	0.1	1.9
East South Central	144	2.8	-0.2	-0.1	2.0	-0.3	0.1	2.3
West South Central	136	2.8	-0.3	0.0	1.9	-0.3	-0.1	2.2
Mountain	49	2.3	-0.6	-0.2	0.0	-0.1	1.2	2.2
Pacific	24	2.5	-0.2	0.2	1.0	-0.1	0.0	2.1
By Payment Classification:								
Urban hospitals	2,049	2.9	0.0	0.0	-0.5	0.1	0.1	2.5
Rural areas	1,152	2.8	0.0	0.1	1.0	-0.2	0.1	2.5
Teaching Status:								
Nonteaching	2,037	2.8	-0.2	0.0	0.0	0.1	0.1	2.2
Fewer than 100 residents	907	2.9	-0.1	0.0	0.1	0.0	0.2	2.5

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2021 Changes (7)[8]
100 or more residents	257	2.8	0.3	0.1	-0.1	-0.1	0.1	2.7
Urban DSH:								
Non-DSH	505	2.8	-0.2	0.1	-0.4	-0.2	0.2	2.2
100 or more beds	1,289	2.9	0.0	-0.1	-0.5	0.2	0.1	2.5
Less than 100 beds	351	2.9	-0.3	-0.1	-0.5	0.2	0.2	2.1
Rural DSH:								
SCH	259	2.4	-0.3	-0.1	0.0	-0.1	0.0	2.1
RRC	545	2.8	0.1	0.1	1.2	-0.2	0.1	2.6
100 or more beds	36	2.9	0.1	0.2	-0.2	-0.3	0.0	2.3
Less than 100 beds	216	2.7	-0.4	0.1	0.6	-0.3	0.2	2.2
Urban teaching and DSH:								
Both teaching and DSH	739	2.9	0.1	0.0	-0.6	0.1	0.1	2.6
Teaching and no DSH	74	2.9	-0.1	0.1	-0.4	-0.2	0.1	2.4
No teaching and DSH	901	2.9	-0.1	-0.1	-0.4	0.4	0.1	2.3
No teaching and no DSH	335	2.8	-0.4	0.1	-0.6	-0.2	0.2	2.2
Special Hospital Types:								
RRC	483	2.9	0.1	0.1	1.2	-0.2	0.2	2.6
SCH	304	2.4	-0.2	0.0	0.0	0.0	0.0	2.1
MDH	145	2.5	-0.4	0.2	0.1	-0.2	0.1	2.0
SCH and RRC	149	2.4	-0.2	0.0	0.5	-0.1	0.1	2.1
MDH and RRC	25	2.6	-0.3	0.0	0.6	-0.1	0.0	2.3
Type of Ownership:								
Voluntary	1,885	2.8	0.0	0.0	0.0	0.0	0.1	2.5

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2021 Changes (7)[8]
Proprietary	827	2.9	-0.1	-0.1	0.0	0.0	0.1	2.4
Government	488	2.8	0.1	0.1	-0.1	0.0	0.0	2.5
Medicare Utilization as a Percent of Inpatient Days:								
0-25	641	2.8	0.1	0.1	-0.5	-0.1	0.0	2.6
25-50	2,114	2.8	0.0	0.0	0.1	0.0	0.1	2.5
50-65	373	2.7	-0.2	0.0	0.4	0.4	0.2	2.2
Over 65	49	2.8	-0.7	-0.2	-0.9	-0.3	0.1	1.7
FY 2021 Reclassifications:								
All Reclassified Hospitals	900	2.8	0.0	0.1	1.5	-0.2	0.1	2.6
Non-Reclassified Hospitals	2,301	2.8	0.0	-0.1	-0.9	0.1	0.1	2.4
Urban Hospitals Reclassified	722	2.8	0.0	0.1	1.3	-0.2	0.1	2.6
Urban Non-Reclassified Hospitals	1,752	2.9	0.0	-0.1	-1.0	0.1	0.1	2.4
Rural Hospitals Reclassified Full Year	309	2.6	-0.3	0.1	2.0	-0.2	0.1	2.2
Rural Non-Reclassified Hospitals Full Year	418	2.6	-0.3	0.0	-0.4	-0.2	0.2	2.1
All Section 401 Reclassified Hospitals	467	2.8	0.1	0.1	1.0	-0.2	0.1	2.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	2.7	-0.3	0.2	2.2	-0.3	0.0	2.1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2019, and hospital cost report data are from reporting periods beginning in FY 2018 and FY 2017.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 2.4 percent update to the national standardized amount and the hospital-specific rate (the estimated 2.4 percent market basket update with the by 0.0 percentage point for the multifactor productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 38 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.99798in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2017 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000426.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2021 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2021. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic reclassification budget neutrality factor of 0.986583.

[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.993433.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2020 to FY 2021 including an estimated decrease in outlier payments of 0.2 percent (from our current estimate of FY 2020 outlier payments of approximately 5.3 percent to 5.1 percent projected for FY 2021 based on the FY 2019 MedPAR data used for this final rule calculated for purposes of this impact analysis). This column also includes the effects of the adoption of the revised labor market area delineations in OMB Bulletin 18-04 and the effects of the transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year.

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a. Effects of the Hospital Update and Other Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this final rule, this column includes the hospital update, including the 2.4 percent market basket update and the 0.0 percentage point for the multifactor productivity adjustment. In addition, as discussed in section II.D. of the preamble of this final rule, this column includes the FY 2021 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we are making a 2.9 percent update to the national standardized amount.

This column also includes the update to the hospital-specific rates which includes the 2.4 percent market basket update together with the 0.0 percentage point for the multifactor productivity adjustment. As a result, we are making a 2.4 percent update to the hospital-specific rates.

Overall, hospitals would experience a 2.8 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate would experience a 2.4 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increase in payments.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this final rule, the FY 2021 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2021, the MS–DRGs are calculated using the FY 2019 MedPAR data grouped to the Version 38 (FY 2021) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 0.99798 to the standardized amount. Hospital categories that generally treat relatively less complex cases, such as rural hospitals and smaller urban hospitals, would experience a decrease in their payments, while hospitals that generally treat relatively more complex cases, such as larger urban hospitals, would experience an increase in their payments under the relative weights. For example, rural hospitals with 50–99 beds and urban hospitals of 99 beds or less would experience a −0.3 and −0.5 percent decrease in payments, respectively. Conversely, urban hospitals of 500 beds or more would experience a +0.2 percent increase in payments.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of the updated wage data using FY 2017 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2021 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01 and 17–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index, and to the FY 2020 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2020 wage index.)

As discussed in section III.A.2.a. of the preamble of this final rule, OMB Bulletin No. 18–04 established revised delineations for statistical areas, and in order to implement these changes for the IPPS, it is necessary to identify the new labor market area delineation for each county and hospital in the country that are affected by the revised OMB delineations. We believe that adopting the revised OMB delineations described in OMB Bulletin No. 18–04 will allow us to maintain a more accurate payment system that reflects the reality of population shifts and labor market conditions. We further believe that using these delineations will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. As discussed in section III.A.2, in this final rule, we are finalizing our proposal to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2021 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2016 and before October 1, 2017. The estimated impact of the updated wage data using the FY 2017 cost report data and the revised OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2020 wage index, based on FY 2016 wage data, the labor-related share of 68.3 percent, under the revised OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2021 pre-reclassification wage index based on FY 2017 wage data with the labor-related share of 68.3 percent, under the revised OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the Version 38 MS–DRG GROUPER constant. The FY 2021 occupational mix adjustment is based on the CY 2016 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2021, we finalizing our proposal to calculate the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 68.3 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2021 wage budget neutrality factor is 1.000426 and the overall payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2017 cost reports. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 1.02 percent compared to FY 2020. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 1.02 percent increase in the national average hourly wage. Of the 3,181 hospitals with wage data for both FYs 2020 and 2021, 1,655 or 52 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2021 relative to FY 2020. These figures reflect changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that this analysis was performed by applying the revised OMB labor market area delineations to the FY 2021 wage data and also by recomputing the FY 2020 final wage data to reflect the revised OMB delineations. (We refer readers to sections III.G. through III.L. of the preamble of this final rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and

adjustments (as reflected in Tables 2 and 3 associated with this final rule, which are available via the internet on the CMS website) is used to adjust the labor-related share of a hospital's standardized amount, either 68.3 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals.

FY 2021 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	7	2
Increase greater than or equal to 5 percent and less than 10 percent	41	0
Increase or decrease less than 5 percent	2,331	722
Decrease greater than or equal to 5 percent and less than 10 percent	87	0
Decrease 10 percent or more	25	5
Unchanged	2	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2021.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we finalizing our proposal to apply an adjustment of 0.986583 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.1 percent. By region, most rural hospital categories would experience increases in payments due to MGCRB reclassifications. Hospitals in the rural West North Central region would experience a decrease in payments due to MGCRB reclassifications, while hospitals in the rural Mountain region would experience no change in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website reflects the reclassifications for FY 2021.

e. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2020 IPPS/LTCH PPS final rules, and this FY 2021 IPPS/LTCH PPS final rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the final rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a FY 2021 rural floor budget neutrality factor of 0.993433 that we applied to the wage index, which will reduce wage indexes by approximately 0.7 percent.

Column 5 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index based on the revised OMB labor market area delineations. The column compares the post-reclassification FY 2021 wage index of providers before the rural floor adjustment and the post-reclassification FY 2021 wage index of providers with the rural floor adjustment based on the revised OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals that do not receive an increase to their wage index from the rural floor adjustment (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) will experience a decrease in payments due to the budget neutrality adjustment that is applied to the wage index nationally. (As finalized in the FY 2020 IPPS/LTCH PPS final rule, we calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103.)

We estimate that 285 hospitals will receive the rural floor in FY 2021. All IPPS hospitals in our model will have their wage indexes reduced by the rural floor budget neutrality adjustment of 0.993433. We project that, in aggregate, rural hospitals will experience a 0.2 percent decrease in payments as a result of the application of the rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas will experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region will experience a 2.3 percent increase in payments primarily due to the application of the rural floor in Massachusetts. Fifty-two urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality adjustment, which will increase payments overall to hospitals in Massachusetts by an estimated $158 million. We estimate that Massachusetts hospitals will receive approximately a 4.1 percent increase in IPPS payments due to the application of the rural floor in FY 2021. Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the rural floor for FY 2021.

f. Effects of the Application of the Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and will increase

payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 44 hospitals located in those States will receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $69 million. Urban hospitals located in the West North Central region will experience an increase in payments by 0.6 percent, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment will receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 212 providers that will receive the out-migration wage adjustment in FY 2021. Rural hospitals generally will qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they will each experience a 0.1 and 0.2 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase will be approximately $51 million.

g. Effects of All FY 2021 Changes (Column 7)

Column 7 shows our estimate of the changes in payments per discharge from FY 2020 and FY 2021, resulting from all changes reflected in this final rule for FY 2021. It includes combined effects of the year-to-year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 2.5 percent for FY 2021 relative to FY 2020 and for this row is primarily driven by the changes reflected in Column 1. Column 7 includes the annual hospital update of 2.9 percent to the national standardized amount. This annual hospital update includes the 2.4 percent market basket update and the 0.0 percentage point multifactor productivity adjustment. As discussed in section II.D. of the preamble of this final rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 2.4 percent hospital update. As described in Column 1, the annual hospital update with the +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates, would result in a 2.5 percent increase in payments in FY 2021 relative to FY 2020. This estimated increase also reflects the effects of the adoption of the revised labor market area delineations in OMB Bulletin 18–04 and the effects of the transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year. Additionally, the estimated increase also reflects an estimated decrease in outlier payments of 0.2 percent (from our current estimate of FY 2020 outlier payments of approximately 5.3 percent to 5.1 percent projected for FY 2021 based on the FY 2019 MedPAR data used for this final rule calculated for purposes of this impact analysis). There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which contribute to our estimate of the changes in payments per discharge from FY 2020 and FY 2021 in Column 7.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.5 percent for FY 2021. Hospitals in urban areas would experience a 2.5 percent increase in payments per discharge in FY 2021 compared to FY 2020. Hospital payments per discharge in rural areas are estimated to increase by 2.2 percent in FY 2021.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2021 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2020 with the estimated average payments per discharge for FY 2021, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

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TABLE II.--IMPACT ANALYSIS OF CHANGES FOR FY 2021 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2020 Payment Per Discharge (2)	Estimated Average FY 2021 Payment Per Discharge (3)	FY 2021 Changes (4)
All Hospitals	3,201	13,485	13,819	2.5
By Geographic Location:				
Urban hospitals	2,462	13,860	14,207	2.5
Rural hospitals	739	10,006	10,222	2.2
Bed Size (Urban):				
0-99 beds	635	10,943	11,163	2.0
100-199 beds	756	11,329	11,607	2.4
200-299 beds	426	12,591	12,899	2.4
300-499 beds	422	13,908	14,245	2.4
500 or more beds	223	17,118	17,579	2.7
Bed Size (Rural):				
0-49 beds	312	8,805	8,978	2.0
50-99 beds	254	9,516	9,717	2.1
100-149 beds	95	9,820	10,036	2.2
150-199 beds	39	10,650	10,891	2.3
200 or more beds	39	11,518	11,777	2.2
Urban by Region:				
New England	112	14,855	15,259	2.7
Middle Atlantic	305	15,698	16,145	2.8
East North Central	381	13,003	13,324	2.5
West North Central	160	13,360	13,623	2.0
South Atlantic	402	12,310	12,619	2.5
East South Central	144	11,760	12,039	2.4
West South Central	364	12,949	13,267	2.5
Mountain	172	14,058	14,307	1.8
Pacific	372	17,286	17,754	2.7
Puerto Rico	50	11,908	12,127	1.8
Rural by Region:				
New England	19	13,896	14,234	2.4
Middle Atlantic	50	9,681	9,896	2.2
East North Central	114	10,278	10,502	2.2
West North Central	89	10,449	10,656	2.0
South Atlantic	114	9,414	9,597	1.9
East South Central	144	8,958	9,168	2.3
West South Central	136	8,748	8,938	2.2
Mountain	49	11,987	12,246	2.2
Pacific	24	13,456	13,745	2.1
By Payment Classification:				
Urban hospitals	2,049	13,488	13,822	2.5
Rural areas	1,152	13,480	13,814	2.5
Teaching Status:				
Nonteaching	2,037	10,940	11,184	2.2
Fewer than 100 residents	907	12,692	13,006	2.5
100 or more residents	257	19,662	20,203	2.7
Urban DSH:				

	Number of Hospitals (1)	Estimated Average FY 2020 Payment Per Discharge (2)	Estimated Average FY 2021 Payment Per Discharge (3)	FY 2021 Changes (4)
Non-DSH	505	11,490	11,743	2.2
100 or more beds	1,289	13,962	14,314	2.5
Less than 100 beds	351	10,154	10,363	2.1
Rural DSH:				
SCH	259	10,974	11,204	2.1
RRC	545	14,106	14,468	2.6
100 or more beds	36	13,470	13,782	2.3
Less than 100 beds	216	8,293	8,478	2.2
Urban teaching and DSH:				
Both teaching and DSH	739	15,168	15,560	2.6
Teaching and no DSH	74	12,367	12,668	2.4
No teaching and DSH	901	11,338	11,598	2.3
No teaching and no DSH	335	10,653	10,891	2.2
Special Hospital Types:				
RRC	483	14,209	14,576	2.6
SCH	304	11,892	12,145	2.1
MDH	145	9,034	9,219	2.0
SCH and RRC	149	12,250	12,512	2.1
MDH and RRC	25	10,354	10,592	2.3
Type of Ownership:				
Voluntary	1,885	13,527	13,864	2.5
Proprietary	827	11,832	12,114	2.4
Government	488	15,477	15,864	2.5
Medicare Utilization as a Percent of Inpatient Days:				
0-25	641	16,602	17,028	2.6
25-50	2,114	13,126	13,452	2.5
50-65	373	10,683	10,920	2.2
Over 65	49	7,885	8,020	1.7
FY 2021 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	900	13,527	13,881	2.6
Non-Reclassified Hospitals	2,301	13,460	13,783	2.4
Urban Hospitals Reclassified	722	14,244	14,621	2.6
Urban Nonreclassified Hospitals	1,752	13,609	13,937	2.4
Rural Hospitals Reclassified Full Year	309	10,183	10,406	2.2
Rural Nonreclassified Hospitals Full Year	418	9,741	9,946	2.1
All Section 401 Reclassified Hospitals:	467	14,725	15,101	2.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	9,402	9,600	2.1

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H. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are implementing various other changes in this final rule. As noted in section I.G. of this regulatory impact analysis, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain changes being implemented in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policies Relating to New Medical Service and Technology Add-On Payments

In section II.G.9.b of the preamble of this final rule, we are revising § 412.87(d)(1) to add drugs approved under FDA's LPAD pathway to the current alternative new technology add-on payment pathway for QIDPs, beginning with discharges occurring on or after October 1, 2021.

Given the relatively recent introduction of the FDA's LPAD pathway there have not been any drugs that were approved under the FDA's LPAD pathway that applied for an NTAP under the IPPS and were not approved for that NTAP. If all of the future LPADs that would have applied for new technology add-on payments would have been approved under existing criteria, this policy has no impact relative to current policy. To the

extent that there are future LPADs that are the subject of applications for new technology add-on payments, and those applications would have been denied under the current new technology add-on payment criteria, this policy is a cost, but that cost is not estimable. We also note that as this policy would be effective beginning with new technology add-on payment applications for FY 2022, there would be no impact of this policy in FY 2021.

b. Change to Announcement of Determinations and Deadline for Consideration of New Medical Service or Technology Applications for Certain Antimicrobial Products

In section II.G.9.c. of the preamble of this final rule, we are revising § 412.87(e) to add a new paragraph (3) which would provide for conditional new technology add-on payment approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

If all of the future antimicrobial products eligible for the alternative pathway for certain antimicrobial products at § 412.87(d) receive marketing authorization by the July 1 deadline specified in § 412.87(e)(2), this policy has no impact. To the extent that there are future antimicrobial products that do not receive marketing authorization by that deadline, but do receive FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments, this policy is a cost, but that cost is not estimable.

c. FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments

In section II.G.4. of the preamble of this final rule, as proposed, we are discontinuing new technology add-on payments for the AQUABEAM System (Aquablation), ERLEADA®, GIAPREZA™, the remede−® System, VABOMERE™, VYXEOS™, the Sentinel® Cerebral Protection System, and KYMRIAH® and YESCARTA® for FY 2021 because these technologies will have been on the U.S. market for 3 years. In addition, as we proposed, as discussed in section II.G.4. of the preamble of this final rule, we are continuing to make new technology add-on payments for AndexXa™, AZEDRA®, BALVERSA™, Cablivi®, ELZONRIS®, Esketamine, Jakafi®, T2 Bacteria Test Panel, XOSPATA®, and ZEMDRI™ in FY 2021 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2) and in conjunction with our change to the calculation of the new technology add-on payments for products approved under the LPAD pathway, the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as QIDPs or approved under the LPAD pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2021 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. The following are estimates for FY 2021 for the 10 technologies for which we are continuing to make new technology add-on payments in FY 2021:

- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for AndexXa™ would increase overall FY 2021 payments by $98,755,313 (maximum add-on payment of $18,281.25 * 5,402 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for AZEDRA® would increase overall FY 2021 payments by $39,260,000 (maximum add-on payment of $98,150 * 400 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for BALVERSA™ would increase overall FY 2021 payments by $178,162 (maximum add-on payment of $3,563.23 * 50 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for Cablivi® would increase overall FY 2021 payments by $4,351,165 (maximum add-on payment of $33,215 * 131 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for ELZONRIS® would increase overall FY 2021 payments by $30,985,668 (maximum add-on payment of $125,448.05 * 247 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for Esketamine would increase overall FY 2021 payments by $6,494,656 (maximum add-on payment of $1,014.79 * 6,400 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for Jakafi® would increase overall FY 2021 payments by $573,469 (maximum add-on payment of $4,096.21 * 140 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for T2 Bacteria Test Panel would increase overall FY 2021 payments by $3,669,803 (maximum add-on payment of $97.50 * 37,639 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for XOSPATA® would increase overall FY 2021 payments by $13,710,938 (maximum add-on payment of $7,312.50 * 1,875 patients).
- Based on the applicant's estimate for FY 2019 we currently estimate that new technology add-on payments for ZEMDRI™ would increase overall FY 2021 payments by $10,209,375 (maximum add-on payment of $4,083.75 * 2,500 patients).

d. FY 2021 Applications for New Technology Add-On Payments

In sections II.G.5. and 6. of the preamble to this final rule, we discuss 15 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2021. We note that three applicants did not receive FDA approval for their technology by the July 1 deadline. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.H.6. of the preamble of this final rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation or are part of the Breakthrough Device program will be considered new and not substantially similar to an existing technology and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still meet the cost criterion.

The following are estimates for FY 2021 for the 6 technologies that we are approving for under the traditional pathway new technology add-on payments beginning in FY 2021.

- Based on the applicant's estimate for FY 2021 we currently estimate that new technology add-on payments for ContaCT would increase overall FY 2021 payments by $72,109,440 (maximum add-on payment of $1,040 * 69,336 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for Eluvia™ Drug-Eluting Vascular Stent System would increase overall FY 2021 payments by $8,944,865 (maximum add-on payment of $3,646.50 * 2,453 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for Hemospray® would increase overall FY 2021 payments by $20,637,500 (maximum add-on payment of $1,625 * 12,700 patients).
- Based on the applicants' estimate for FY 2021, we currently estimate that new technology add-on payments for TECENTRIQ® and IMFINZI® would increase overall FY 2021 payments by $29,538,866 (maximum add-on payment of $6,875.90 * 4,296 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for Soliris® would increase overall FY 2021 payments by $290,012,580 (maximum add-on payment of $21,199.75 * 13,680 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for the SpineJack System would increase overall FY 2021 payments by $5,745,220 (maximum add-on payment of $3,654.72 * 1,572 patients).

As also discussed in section II.G.6. of the preamble of this final rule, for FY 2021 we are approving seven alternative pathway applicant technologies (2 Breakthrough devices and 5 QIDPs) and conditionally approving one alternative pathway applicant technology (1 QIDP) for FY 2021that one

applicant did not receive FDA approval by the July 1 deadline (as discussed in section II.G.9.c. of the preamble of this final rule). We note that one applicant under the alternative pathway for Breakthrough Devices did not receive FDA approval by the July 1 deadline.

The following are estimates for FY 2021 for the eight alternative pathway technologies that we are approving or conditionally approving for new technology add-on payments beginning in FY 2021.

- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for the BAROSTIM NEO™ System would increase overall FY 2021 payments by $16,425,500 (maximum add-on payment of $22,750 * 722 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for FETROJA® could increase overall FY 2021 payments by $50,330,710 (maximum add-on payment of $7,919.86 * 6,355 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for CONTEPO would increase overall FY 2021 payments by $20,369,531 (maximum add-on payment of $2,343.75 * 8,691 patients) under our conditional approval policy for certain antimicrobial products depending on the quarter in which it ultimately receives FDA marketing authorization.
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for NUZYRA® would increase overall FY 2021 payments by $26,235,698 (maximum add-on payment of $1,522.50 * 16,899 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for Optimizer System would increase overall FY 2021 payments by $22,425,000 (maximum add-on payment of $14,950 * 1,500 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for RECARBRIO™ would increase overall FY 2021 payments by $2,691,978 (maximum add-on payment of $3,532.78 * 762 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for XENELTA™ would increase overall FY 2021 payments by $44,965,085 (maximum add-on payment of $1,275.75 * 35,246 patients).
- Based on the applicant's estimate for FY 2021, we currently estimate that new technology add-on payments for ZERBAXA® would increase overall FY 2021 payments by $55,324,327 (maximum add-on payment of $1,836.98 * 30,117 patients).

2. Effects of Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the MS–DRG Special Payment Policy

In section IV.A. of the preamble of this final rule, we discuss our changes to the list of MS–DRGs subject to the postacute care transfer policy and the MS DRG special payment policy for FY 2021. As reflected in Table 5 listed in section VI. of the Addendum to this final rule (which is available via the internet on the CMS website), using criteria set forth in regulations at 42 CFR 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which new or revised MS–DRGs would qualify for the postacute care transfer and MS–DRG special payment policies. As a result of our revisions to the MS–DRG classifications for FY 2021, which are discussed in section II.F. of the preamble of this final rule, we are adding two MS–DRGs to the list of MS–DRGs that will be subject to the postacute care transfer policy and the MS–DRG special payment policy. Column 2 of Table I in this Appendix A shows the effects of the changes to the MS–DRGs and the relative payment weights and the application of the recalibration budget neutrality factor to the standardized amounts.

Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the changes due to the MS–DRGs and relative payment weights account for and include changes as a result of the changes to the MS–DRGs subject to the MS–DRG postacute care transfer and MS–DRG special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to the MS–DRG reclassification policies for FY 2021.

3. Effects of the Changes to Uncompensated Care Payments for FY 2021

As discussed in section IV.G. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, we are establishing the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2021 is $8,290,014,520.96. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 72.86 percent. For FY 2020, the amount available to be distributed for uncompensated care was $8,350,599,096.04, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 67.14 percent. To calculate Factor 3 for FY 2021, we used information on uncompensated care costs from Worksheet S–10 of hospitals' FY 2017 cost reports for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service and Tribal hospitals, for which we are finalizing our proposal to continue to use low-income insured days from FY 2013 cost reports and FY 2018 SSI days to determine Factor 3. For purposes of this final rule, we used uncompensated care data from the HCRIS database, as updated through June 30, 2020, Medicaid days from hospitals' FY 2013 cost reports from the same extract of HCRIS, and SSI days from the FY 2018 SSI ratios. For a complete discussion of the methodology for calculating Factor 3, we refer readers to section IV.G.4. of the preamble of this final rule.

To estimate the impact of the combined effect of the changes to Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments, we compared total uncompensated care payments estimated in the FY 2020 IPPS/LTCH PPS final rule to total uncompensated care payments estimated in this FY 2021 IPPS/LTCH PPS final rule. For FY 2020, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 67.14 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2020 IPPS/LTCH PPS final rule. For FY 2021, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 72.86 percent and multiplied by a Factor 3 calculated using the methodology described previously.

Our analysis included 2,401 hospitals that are projected to be eligible for DSH in FY 2021. It did not include hospitals that terminated their participation from the Medicare program as of July 10, 2020, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. The 22 hospitals participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the nonsurviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2021, by hospital characteristic, is presented in the following table.

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Modeled Uncompensated Care Payments for Estimated FY 2021 DSHs by Hospital Type: Uncompensated Care Payments ($ in Millions)* - from FY 2020 to FY 2021					
	Number of Estimated DSHs (1)	FY 2020 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2021 Final Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2020 - FY 2021 ($ in millions) (4)	Percent Change** (5)
Total	2,401	$8,351	$8,290	-61	-0.73%
By Geographic Location					
Urban Hospitals	1,913	7,826	7,795	-31	-0.39
Large Urban Areas	992	4,793	4,824	31	0.65
Other Urban Areas	921	3,033	2,971	-62	-2.04
Rural Hospitals	488	525	495	-30	-5.70
Bed Size (Urban)					
0 to 99 Beds	322	282	289	7	2.42
100 to 249 Beds	831	1,920	1,899	-21	-1.10
250+ Beds	760	5,624	5,607	-16	-0.29
Bed Size (Rural)					
0 to 99 Beds	374	297	275	-21	-7.22
100 to 249 Beds	101	180	168	-12	-6.73
250+ Beds	13	48	52	4	7.44
Urban by Region					
New England	93	251	226	-24	-9.68
Middle Atlantic	235	1,055	981	-74	-7.03
South Atlantic	316	824	863	38	4.62
East North Central	100	381	404	22	5.90
East South Central	312	1,973	2,023	50	2.55
West North Central	128	495	504	8	1.70
West South Central	244	1,701	1,632	-70	-4.11
Mountain	127	373	335	-38	-10.14
Pacific	317	663	722	58	8.82
Puerto Rico	41	109	107	-2	-2.11
Rural by Region					
New England	9	17	15	-1	-7.37
Middle Atlantic	23	20	16	-5	-22.61

Modeled Uncompensated Care Payments for Estimated FY 2021 DSHs by Hospital Type: Uncompensated Care Payments ($ in Millions)* - from FY 2020 to FY 2021					
	Number of Estimated DSHs (1)	FY 2020 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2021 Final Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2020 - FY 2021 ($ in millions) (4)	Percent Change** (5)
South Atlantic	70	61	61	0	-0.57
East North Central	32	32	32	0	-0.24
East South Central	87	141	134	-6	-4.40
West North Central	122	109	102	-6	-5.76
West South Central	111	116	108	-8	-7.13
Mountain	28	23	20	-4	-15.24
Pacific	6	6	7	1	8.95
By Payment Classification					
Urban Hospitals	1,574	6,095	6,102	7	0.11
Large Urban Areas	874	3,953	3,998	45	1.13
Other Urban Areas	700	2,142	2,104	-38	-1.78
Rural Hospitals	827	2,255	2,188	-67	-2.99
Teaching Status					
Nonteaching	1,396	2,469	2,448	-21	-0.84
Fewer than 100 residents	751	2,872	2,850	-22	-0.77
100 or more residents	254	3,010	2,992	-18	-0.59
Type of Ownership					
Voluntary	1,443	4,557	4,560	3	0.06
Proprietary	576	1,247	1,216	-32	-2.55
Government	382	2,546	2,515	-32	-1.25
Medicare Utilization Percent***					
0 to 25	550	3,399	3,388	-11	-0.34
25 to 50	1,629	4,745	4,701	-44	-0.94
50 to 65	201	201	196	-5	-2.31
Greater than 65	20	5	6	0	0.62

Source: Dobson | DaVanzo analysis of 2013 and 2017 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $8,351 million in FY 2020 and $8,290 million in FY 2021.

** Percentage change is determined as the difference between Medicare uncompensated care payments modeled for this FY 2021 IPPS/LTCH PPS final rule (column 3) and Medicare uncompensated care payments modeled for the FY 2020 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2020 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

***Hospitals with missing or unknown Medicare utilization are not shown in table.

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The changes in projected uncompensated care payments for FY 2021 in relation to the uncompensated care payments for FY 2020 are driven by a decrease in Factor 1 and an increase in Factor 2, as well as by a decrease in the number of hospitals projected to be eligible to receive DSH in FY 2021 relative to FY 2020. Factor 1 has decreased from $12.438 billion to $11.378 billion, while the percent change in the percent of individuals who are uninsured (Factor 2) has increased from 67.14 percent to 72.86 percent. Based on the changes in these two factors, the impact analysis found that, across all projected DSH eligible hospitals, FY 2021 uncompensated care payments are estimated at approximately $8.290 billion, or a decrease of approximately 0.73 percent from FY 2020 uncompensated care payments (approximately $8.351 billion). While these changes will result in a net decrease in the amount available to be distributed in uncompensated care payments, the projected payment decreases vary by hospital type. This redistribution of uncompensated care payments is caused by changes in Factor 3. As seen in the previous table, a percent change lower than negative 0.73 percent indicates that hospitals within the specified category are projected to experience a larger decrease in uncompensated care payments, on average, compared to the universe of projected FY 2021 DSH hospitals. Conversely, a percent change greater than negative 0.73 percent indicates that a hospital type is projected to have a smaller decrease than the overall average. Similarly, a positive percent change indicates an increase in uncompensated care payments. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported in the Worksheet S–10, or number of Medicaid days and SSI days for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, used in the Factor 3 computation.

Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive a 5.7 percent decrease in uncompensated care payments,

while urban hospitals are projected to receive a 0.39 percent decrease in uncompensated care payments. Larger urban hospitals, however, are projected to receive a 0.65 percent increase in uncompensated care payments and hospitals in other urban areas a 2.04 percent decrease.

By bed size, smaller rural hospitals are projected to receive the largest decreases in uncompensated care payments. Rural hospitals with 0–99 beds are projected to receive a 7.22 percent payment decrease, and rural hospitals with 100–249 beds are projected to receive a 6.73 percent decrease. These decreases for smaller rural hospitals are greater than the overall hospital average. However, larger rural hospitals with 250+ beds are projected to receive a 7.44 percent payment increase. In contrast, the smallest urban hospitals (0–99 beds) are projected to receive an increase in uncompensated care payments of 2.42 percent, while urban hospitals with 100–249 beds are projected to receive a decrease of 1.10 percent, and larger urban hospitals with 250+ beds projected to receive a 0.29 percent decrease in uncompensated care payments, which is less than the overall hospital average.

By region, rural hospitals are expected to receive larger than average decreases in uncompensated care payments in all Regions, except for rural hospitals in the South Atlantic and East North Central Regions, which are projected to receive smaller than average decreases, and hospitals in the Pacific Region, which are projected to receive an increase in uncompensated care payments of 8.95 percent. Urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, the Middle Atlantic, West South Central, and Mountain Regions, as well as urban hospitals in Puerto Rico, are projected to receive larger than average decreases in uncompensated care payments. While hospitals in the South Atlantic, East North Central, East South Central, West North Central and Pacific Regions are projected to receive increases in uncompensated care payments.

By payment classification, hospitals in urban areas overall are expected to receive a 0.11 percent increase in uncompensated care payments, with hospitals in large urban areas are expected to see an increase in uncompensated care payments of 1.13 percent, while hospitals in other urban areas are expected to receive a decrease of 1.78 percent. In contrast, hospitals in rural areas are projected to receive a decrease in uncompensated care payments of 2.99 percent.

Nonteaching hospitals are projected to receive a payment decrease of 0.84 percent, teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 0.77 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 0.59 percent. All of these decreases are consistent with the overall hospital average. Proprietary and government hospitals are projected to receive larger than average decreases of 2.55 and 1.25 percent respectively, while voluntary hospitals are expected to receive a payment increase of 0.06 percent. Hospitals with less than 50 percent Medicare utilization are projected to receive decreases in uncompensated care payments consistent with the overall hospital average percent change, while hospitals with 50 to 65 percent Medicare utilization are projected to receive a larger than average decrease of 2.31 percent. Hospitals with greater than 65 percent Medicare utilization are projected to receive an increase of 0.62 percent.

4. Effects of Reductions Under the Hospital Readmissions Reduction Program for FY 2021

In section IV.G. of the preamble of this final rule, we discuss our proposed policies for the FY 2021 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this final rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. Hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare FFS and managed care stays between July 1, 2016 and June 30, 2019 (that is the FY 2021 Hospital Readmissions Reduction Program's performance period). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. To analyze the results by hospital characteristic, we used the FY 2021 Hospital IPPS Proposed Rule Impact File.

These analyses include 2,986 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2016 and June 30, 2019. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 82.17 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 89.70 percent of eligible hospitals with fewer than 100 residents and 92.64 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristic. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2018 and September 30, 2019 (FY 2019). For example, the penalty as a share of payments for urban hospitals is 0.68 percent. This means that total penalties for all urban hospitals are 0.68 percent of total payments for urban hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

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Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2021 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a Share of Payments[d] (%)**
All Hospitals	2,986	2,545	85.23	0.68
Geographic Location[e] (n= 2,985)				
Urban hospitals	2,256	1,958	86.79	0.68
1-99 beds	516	369	71.51	0.84
100-199 beds	698	634	90.83	0.83
200-299 beds	417	386	92.57	0.76
300-399 beds	265	243	91.70	0.67
400-499 beds	140	125	89.29	0.61
500 or more beds	220	201	91.36	0.54
Rural hospitals	729	586	80.38	0.68
1-49 beds	290	212	73.10	0.60
50-99 beds	260	209	80.38	0.71
100-149 beds	96	87	90.63	0.60
150-199 beds	44	40	90.91	0.68
200 or more beds	39	38	97.44	0.73
Teaching Status[f] (n= 2,985)				
Non-teaching	1,873	1,539	82.17	0.79
Teaching, fewer than 100 residents	854	766	89.70	0.69
Teaching, 100 or more residents	258	239	92.64	0.50
Ownership Type (n= 2,985)				
Government	460	383	83.26	0.52
Proprietary	740	595	80.41	1.02
Voluntary	1,785	1,566	87.73	0.63
Safety-net Status[g] (n= 2,985)				
Safety-net hospitals	592	519	87.67	0.56
Non-safety-net hospitals	2,393	2,025	84.62	0.71
Disproportionate Share Hospital (DSH) Patient Percentage[h] (n=2,985)				
0-24	1,231	1,005	81.64	0.77
25-49	1,414	1,243	87.91	0.63
50-64	194	167	86.08	0.67
65 and over	146	129	88.36	0.52
Medicare Cost Report (MCR) Percentage[i] (n= 2,976)				
0-24	480	412	85.83	0.49
25-49	2,070	1,782	86.09	0.69
50-64	374	310	82.89	0.93
65 and over	52	35	67.31	0.48
Region (n= 2,985)				
New England	125	113	90.40	0.92
Middle Atlantic	339	317	93.51	0.74
South Atlantic	502	459	91.43	0.74
East North Central	468	394	84.19	0.66
East South Central	274	241	87.96	0.82
West North Central	240	187	77.92	0.44
West South Central	459	380	82.79	0.67
Mountain	217	161	74.19	0.53
Pacific	361	292	80.89	0.50

Source: The table results are based on the estimated FY 2021 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The estimated FY 2021 payment adjustment factors are based on discharges between July 1, 2016 and June 30, 2019 (the FY 2021 Hospital Readmissions Reduction Program performance period). Although data from all subsection (d) and Maryland hospitals are used in calculations of the ERRs, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2020 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are stratified into quintiles based on the proportion of Medicare FFS and managed care dual-eligible stays for the 3-year performance period. Hospital characteristics are from the FY 2021 Hospital IPPS proposed rule impact file.

Footnotes:

[a] This column is the number of applicable hospitals with the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. MedPAR data from October 1, 2018 through September 30, 2019 (FY 2019) are used to estimate the total base operating DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location (n=2,985; missing=1), teaching status (n=2,985; missing=1), ownership type (n=2,985; missing=1), safety-net status (n=2,985; missing=1), DSH patient percentage (n=2,985; missing=1), MCR percentage (n=2,976; missing=10), and region (n=2,985; missing=1).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[i] MCR percentage is the percentage of total inpatient stays from Medicare patients.

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We did not receive any public comments regarding the impact of our proposals.

5. Effects of Requirements Under the FY 2021 Hospital Value-Based Purchasing (VBP) Program

In section IV.L. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2021 through a reduction to the FY 2021 base operating DRG payment amounts for discharges during the fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2021 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.L.1.b. of the preamble of this final rule, we estimated the available pool of funds for value-based incentive payments in the FY 2021 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payment amounts, or a total of approximately $1.9 billion. This estimated available pool for FY 2021 is based on the historical pool of hospitals that were eligible to participate in the FY 2020 program year and the payment information from the March 2020 update to the FY 2019 MedPAR file.

The estimated impacts of the FY 2021 program year by hospital characteristic, found in the table in this section, are based on historical TPSs. We used the FY 2020 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the March 2020 update to the FY 2019 MedPAR file. The proxy adjustment factors can be found in Table 16A associated with this final rule (available via the internet on the CMS website at *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-proposed-rule-home-page#Tables*).

The impact analysis shows that, for the FY 2021 program year, the number of hospitals that are expected to receive an increase in their base operating DRG payment amount is higher than the number of hospitals that are expected to receive a decrease. On average, among urban hospitals, hospitals in the West North Central region are expected to have the largest positive percent change in base operating DRG payment amounts, and among rural hospitals, hospitals in the Pacific region are expected to have the largest positive percent change in base operating DRG payment amounts. Urban Middle Atlantic, Urban East South Central, and Urban West South Central regions are expected to experience, on average, a decrease in base operating DRG payment amounts. All other regions, both urban and rural, are expected to experience, on average, an increase in base operating DRG payment amounts.

As DSH patient percentage increases, the average percent change in base operating DRG payment amounts is expected to decrease. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the average percent change in base operating DRG payment amounts is expected to increase for MCR percent 0 to 65, but for MCR percent greater than 65, the average percent change in base operating DRG payment amounts is expected to decrease. On average, teaching hospitals are expected to have a decrease in base operating DRG payment amounts while non-teaching hospitals are expected to have an increase in base operating DRG payment amounts.

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Impact Analysis of Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2021 Hospital VBP Program		
	Number of Hospitals	**Average Net Percentage Payment Adjustment**
BY GEOGRAPHIC LOCATION:		
All Hospitals	**2,731**	**0.165%**
Large Urban	1,090	0.086%
Other Urban	1,016	0.079%
Rural Area	625	0.444%
Missing*		
Urban hospitals	***2,106***	***0.083%***
0-99 beds	359	0.503%
100-199 beds	696	0.150%
200-299 beds	428	-0.044%
300-499 beds	405	-0.152%
500 or more beds	218	-0.141%
Rural hospitals	***625***	***0.444%***
0-49 beds	198	0.639%
50-99 beds	251	0.515%
100-149 beds	94	0.308%
150-199 beds	43	-0.092%
200 or more beds	39	-0.081%
BY REGION:		
Urban By Region	**2,106**	**0.083%**

New England	106	0.091%
Middle Atlantic	278	-0.043%
South Atlantic	378	0.009%
East North Central	337	0.169%
East South Central	126	-0.105%
West North Central	133	0.353%
West South Central	259	-0.021%
Mountain	147	0.104%
Pacific	342	0.212%
Rural By Region	**625**	**0.444%**
New England	18	0.500%
Middle Atlantic	43	0.353%
South Atlantic	97	0.308%
East North Central	109	0.617%
East South Central	114	0.250%
West North Central	77	0.612%
West South Central	97	0.324%
Mountain	46	0.689%
Pacific	24	0.730%
By MCR Percent		
0-25	475	0.063%
25-50	1,922	0.168%
50-65	312	0.311%
Over 65	20	0.093%
Missing	2	-0.154%
BY DSH Percent:		
0-25	1,058	0.274%
25-50	1,355	0.111%
50-65	183	0.032%
Over 65	135	0.036%
Missing		
BY TEACHING STATUS:		
Non-Teaching	1,618	0.293%
Teaching	1,113	-0.019%

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Actual FY 2021 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2021 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2020 program year were used for the updated impact analysis in this final rule. We did not receive any public comments regarding the financial impact of our proposals.

6. Effects of Requirements Under the HAC Reduction Program for FY 2021

We are presenting the estimated impact of the FY 2021 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic. These FY 2021 HAC Reduction Program results were calculated using the Equal Measure Weights approach finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41486 through 41489). Each hospital's Total HAC Score was calculated as the equally weighted average of the hospital's measure scores. The table in this section presents the estimated proportion of hospitals in the worst performing quartile of Total HAC Scores by hospital characteristic. Hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results are based on Medicare FFS discharges from July 1, 2017 through June 30, 2019 and version 10.0 of the PSI software. Hospitals' measure results for CDC Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2018 and December 31, 2019. To analyze the results by hospital characteristic, we used the FY 2021 Proposed Rule Impact File.

This table includes 3,111 non-Maryland hospitals with a FY 2021 Total HAC Score. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Of these 3,111 hospitals, 3,102 hospitals had information for geographic location with bed size, Safety-net status, DSH percent, teaching status and ownership; 3,111 had information on region; and 3,084 had information for MCR percent. The first column presents a breakdown of each characteristic.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2021 HAC Reduction Program. For example, with regard to teaching status, 425 hospitals out of 1,968 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 224 out of 876 hospitals with fewer than 100 residents and 123 out of 258 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2021 HAC Reduction Program. For example, 21.6 percent of the 1,968 hospitals characterized as non-teaching hospitals, 25.6 percent of the 876 teaching hospitals with fewer than 100 residents, and 47.7 percent of the 258 teaching hospitals with 100 or more

residents would be subject to a payment reduction.

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Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2021 HAC Reduction Program (by Hospital Characteristic)			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,111	777	25
By Geographic Location (n = 3,102)[d]			
Urban hospitals	**2,357**	**602**	**25.5**
1-99 beds	588	108	18.4
100-199 beds	712	175	24.6
200-299 beds	430	115	26.7
300-399 beds	266	74	27.8
400-499 beds	141	44	31.2
500 or more beds	220	86	39.1
Rural hospitals	**745**	**170**	**22.8**
1-49 beds	305	71	23.3
50-99 beds	260	53	20.4
100-149 beds	97	22	22.7
150-199 beds	44	15	34.1
200 or more beds	39	9	23.1
By Safety-Net Status[e] (n = 3,102)			
Non-safety net	2,477	550	22.2
Safety-net	625	222	35.5
By DSH Percent[f] (n = 3,102)			
0-24	1,298	258	19.9
25-49	1,437	382	26.6
50-64	203	71	35
65 and over	164	61	37.2
By Teaching Status[g] (n =3,102)			
Non-teaching	1,968	425	21.6
Fewer than 100 residents	876	224	25.6
100 or more residents	258	123	47.7
By Ownership[h] (n = 3,102)			
Voluntary	1,837	444	24.2

Proprietary	788	162	20.6
Government	477	166	34.8
By MCR Percent[i] (n = 3,084)			
0-24	551	154	27.9
25-49	2,090	498	23.8
50-64	383	99	25.8
65 and over	60	13	21.7
By Region[j] (n= 3,111)			
New England	130	45	34.6
Mid-Atlantic	347	107	30.8
South Atlantic	512	136	26.6
East North Central	483	115	23.8
East South Central	286	71	24.8
West North Central	248	59	23.8
West South Central	484	96	19.8
Mountain	231	52	22.5
Pacific	390	96	24.6

Source: FY 2021 HAC Reduction Program final rule Results are based on CMS PSI 90 data from July 1, 2017 through June 30, 2019 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 1, 2018 through December 31, 2019. Hospital Characteristics are based on the FY 2021 Proposed Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2021 Total HAC Score (N = 3,111). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, and teaching status (n = 3,102).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 3,102)

[i] Not all hospitals had data for MCR percent (n = 3,084).

[j] All hospitals had data for Region (n = 3,111)

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We did not receive any public comments regarding the financial impact of our proposals.

7. Policy Change Related to Medical Residents Affected by Residency Program or Teaching Hospital Closure

In section IV.N. of the preamble of this final rule, we are amending the Medicare policy with regard to closing teaching hospitals and closing residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and the incentives of home and receiving hospitals with regard to seamless Medicare IME and direct GME funding. There are no new Medicare funded slots being created by this amendment; as under current policy, the maximum number of FTE cap slots that may be transferred with displaced residents is the number equal to the closing hospital's IME and direct GME FTE caps. Additionally, all of the funding for residents due to a hospital closure would eventually be transferred permanently to new hospitals under current law (section 5506 of the Affordable Care Act, which provides for permanent redistribution of slots due to hospital closure. As a result, we believe that ultimately, there is no new cost generated for the Medicare program as a result of this amendment.

8. Effect of the Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

Section 108 of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94) provides that, effective for cost reporting periods beginning on or after October 1, 2020, payment to a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and that the Secretary shall specify the items included in such hematopoietic stem cell acquisition in rulemaking. This statutory provision also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner. Our implementation of section 108 of the Further Consolidated Appropriations Act, 2020 is discussed in section II.H. of the preamble of this final rule, including our adjustment to the standardized amount to ensure the effects of the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, as required under that law.

9. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2021

In section IV.O. of the preamble of this final rule for FY 2021, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, and more recently, by section 15003 of Public Law 114–255, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 15003 of Public Law 114–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial

5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election to discontinue participation. Furthermore, section 15003 of Public Law 114–255 requires that, during the second 5 years of the 10-year extension period, the Secretary shall provide for participation under the demonstration during the second 5 years of the 10-year extension period for hospitals that are not described in section 410A(g)(4) of Public Law 108–173.

Section 15003 of Public Law 114–255 also requires that no later than 120 days after enactment of Public Law 114–255 that the Secretary issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by Public Law 111–148 is not exceeded. Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality).

In the preamble to this final rule, we described the terms of participation for the extension period authorized by Public Law 114–255. In the FY 2018 IPPS/LTCH PPS final rule, we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those among the hospitals that had previously participated and were choosing to participate in the second 5-year extension period. According to our finalized policy, each of these previously participating hospitals began the second 5 years of the 10-year extension period on the date immediately after the date the period of performance under the 5-year extension period ended. Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act elected to continue in the second 5-year extension period, while 13 additional hospitals were selected to participate. One of the hospitals selected in 2017 withdrew from the demonstration prior to beginning participation on July 1, 2018, while each of the remaining newly participating hospitals began its 5-year period of participation effective the start of the first cost reporting period on or after October 1, 2017. In addition, one among the previously participating hospitals closed effective January 2019, while two have withdrawn effective September 1 and October 1, 2019, respectively. Therefore, 27 hospitals were participating in the demonstration as of this date—15 previously participating and 12 newly participating. For four of the previously participating hospitals, this 5-year period of participation will end during FY 2020; while one of the previously participating hospitals, scheduled to end in 2021, chose in February of this past year to withdraw effective September 2019. Therefore, the budget neutrality calculations in this final rule are based on 22 hospitals. For seven of the remaining 10 hospitals among the original group, participation will end during FY 2021, with participation ending for the other three on December 31, 2021. The newly participating hospitals are all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

In the FY 2018 IPPS/LTCH PPS final rule, we finalized the budget neutrality methodology in accordance with our policies for implementing the demonstration, adopting the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this final rule, the resulting amount applicable to FY 2021 is $39,825,670, which we are including in the budget neutrality offset adjustment for FY 2021. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we will continue this general procedure. All finalized cost reports are not yet all available for the 19 hospitals that completed a cost reporting period beginning in FY 2016 according to the demonstration cost-based payment methodology. Therefore, we are expecting to include in the FY2022 IPPS/LTCH PPS proposed and final rules the difference between the actual costs of the demonstration as determined from these cost reports and the estimated costs as determined in the FY 2016 final rule.

For this final rule for FY 2021, the total amount that we are applying to the national IPPS rates is $39,825,670.

Comment: A commenter expressed support for the continuation of the program, but said, that as a demonstration, the program does not offer long-term financial sustainability needed to maintain health care access in rural areas.

Response: We appreciate the comment. We have conducted the demonstration program in accordance with Congressional mandates.

10. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.B.2. of the preamble of this final rule we discuss the implementation of the FCHIP demonstration, which allowed eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for the demonstration will be based on the demonstration period of August 1, 2016, through July 31, 2019. The demonstration included three intervention prongs, under which specific waivers of Medicare payment rules allowed for enhanced payment: Telehealth, skilled nursing facility/nursing facility services, and ambulance services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. (We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), but did not make any changes to the policy that was adopted in FY 2017.)

We specified the payment enhancements for the demonstration and selected CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, in the FY 2017 IPPS/LTCH PPS final rule we adopted a contingency plan (81 FR 57064 through 57065) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the

event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAHs. Therefore, we would make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by this provider category. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Under the policy adopted in FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped beginning in CY 2020. Based on the currently available data, the determination of budget neutrality results is preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remains uncertain. Therefore, in this final rule, we are finalizing our proposal in the FY 2021 IPPS/LTCH PPS proposed rule to revise the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment. We will revisit this policy in rulemaking for FY 2022 when we expect to have complete data for the demonstration period. Since our data analysis is incomplete, it is not possible to determine the impact of this policy for any national payment system for FY 2021.

11. Effects of the Submission of Electronic Medical Records to Quality Improvement Organizations (QIOs)

In section IX.A. of this final rule, we specify the changes we are adopting regarding the reimbursement to providers, practitioners and institutions for electronic submission of patient records required for QIO purposes. Over the last several years, numerous healthcare providers subject to QIO review activity under §§ 476.78 and 480.111 have requested reimbursement for submitting requested patient records in an electronic format. However, our regulations concerning reimbursement to providers and practitioners for submitting patient records and information required for QIO review activity under § 476.78 only permitted reimbursement for records sent via photocopying and mailing or facsimile. This had the unintended consequence of discouraging providers from using the more efficient and cost effective means of submitting patient records and information to the QIOs in an electronic format solely because reimbursement was available only for patient records and information submitted via photocopying and mailing.

The updates we are making to the regulation with this final rule respond to requests from providers, by addressing reimbursement for submitting records to the QIO in electronic format as well as by photocopying and mailing and facsimile. According to 2017 Office of National Coordinator survey result, 96 percent of all non-federal acute care hospitals possessed certified health IT. Ninety-nine percent of large hospitals (more than 300 beds) had certified health IT, while 97 percent of medium-sized hospitals (more than 100 beds) had certified health IT. Also nearly 9 in 10 (86 percent) of office-based physicians had adopted any EHR, and nearly 4 in 5 (80 percent) had adopted a certified EHR (*https://dashboard.healthit.gov/quickstats/quickstats.php*). Given the widespread adoption of the Certified Electronic Health Record Technology (CEHRT), we believe that the providers and QIOs now have the capacity to send and receive patient records in electronic format. In light of these facts, we believe that it is now appropriate to require providers, practitioners and institutions to submit patient records to the QIOs in electronic format. Our updates to the regulations also provide appropriate reimbursement for patient records submitted to the QIOs in an electronic format. We believe these changes will result in a large shift among providers, practitioners and institutions, which are subject to QIO review and which submit information and documents for the QIOs to perform their QIO functions under §§ 476.78 and 480.111, toward submitting patient records in electronic format. As discussed later in this section, we believe these provisions will help reduce our costs for QIO-labor associated with scanning and uploading patient records they receive by mail or facsimile, as well as reducing the time to complete QIO reviews as electronic records are generally easier to store and search. Thus, the requirement for providers to submit patient records to QIOs in electronic format will be advantageous for CMS. Providers and practitioners who are unable to send patient records to the QIOs in an electronic format will be able to obtain a waiver to permit them to submit records to the QIO via facsimile or photocopying and mailing under this provision. We proposed an updated reimbursement rate for patient records submitted by facsimile or by photocopying and mailing to account for current wage and materials costs, and a waiver process that is minimally burdensome for providers, practitioners, and institutions.

We expect that implementation of the requirement for providers and practitioners to submit records to QIOs in and electronic format will have significant implications in terms of cost savings. Because CMS reimburses the QIOs directly for all payments to providers and practitioners for sending records to the QIOs and pays QIOs for their work, including the additional time and overhead expenses related to using paper records instead of electronic records. Therefore, any cost savings to the QIOs as a result of the adoption of electronic formats for submission of patient records would result in a cost savings to CMS. The less it costs to send records to the QIOs, the less CMS has to reimburse for those costs.

To estimate savings, we assumed 100 percent compliance with the proposed requirements at § 476.78(c). Although we assumed that 20 percent of providers, practitioners or institutions would seek a waiver, given the percentage of providers that currently have access to Certified Electronic Health Record Technology (CEHRT), we believe that ultimately all providers will be able to submit patient records in electronic format in the future.

We did not receive any comments regarding our proposal to require providers to submit requested patient records to QIOs for the purpose of fulfilling one or more QIO functions unless they have an approved waiver. We continue to believe that it is reasonable to require providers to submit patient records in electronic format unless they have a QIO approved waiver.

We estimated the total savings by subtracting the total cost of sending records electronically from the total cost of sending records by photocopying and mailing. Over the last 5 years, providers and practitioners have sent about 1.2 million patient records to the QIOs, totaling approximately 342 million pages of documents. Currently, providers are reimbursed at the rate of $0.12 per page, which results in a total reimbursement cost of about $41 million over 5 years. In contrast, we proposed, sending 1.2 million records electronically at a rate of reimbursement of $3 per record would amount to a total reimbursement cost of roughly $3.6 million. Subtracting $3.6 million (the estimated cost of sending records electronically over 5 years) from $41 million (the cost of sending records by fax or by mail), would result in a total estimated savings to CMS of $37.4 million. We would save money on the efforts of the QIOs to scan and process the paper records before sending them on for review electronically. However, these longer-run savings would be preceded by short-run transition costs, which we have not estimated.

Based on our estimates for case volume set forth previously, and assuming the QIOs cost for scanning and labor is $0.10 per page, based on the information set out in Table 1 of this Appendix, we estimate that it would save CMS about $34.3 million if the agency no longer needed to scan 342 million pages of records. Savings in payments for the labor and materials costs provided to both providers and QIOs for photocopying, scanning, and uploading results in total savings to CMS of $71.8 million. Tables 2 and 3 of this Appendix illustrate the cost savings to CMS over 5 years.

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TABLE 1--ESTIMATED PROVIDERS REIMBURSEMENT AND LABOR COST SAVINGS FOR CMS

Estimated Payment to Providers						
QIO Review Type	**5-Year Case Volume**	**Average Number of Pages per Medical Record**	**Total Number of Pages per Review Type**	**Estimated Cost for Electronic Transmission ($3 per Medical Record)**	**Labor Hours ****	**Estimated Total Cost of Photocopying (Based on $0.12 per page)**
Hospital Discharge Appeal Review (Weichardt QOC)	159,343	408	65,011,944	$478,029	180,589	$7,801,433
Fee for Service Non-coverage Review (BIPA Appeals)	171,239	247	42,296,033	$513,717	117,489	$5,075,524
Medicare Advantage Non-coverage Review (Grijalva Appeals)	394,684	247	97,486,948	$1,184,052	270,797	$11,698,434
Hospital Inpatient Claims Reviews						
Hospital Inpatient Short Stay Claims Review	197,000	226	44,522,000	$591,000	123,672	$5,342,640
Hospital Inpatient DRG Claims Validation	156,129	509	79,469,661	$468,387	220,749	$9,536,359
Other Focused Claims Review	80,475	167	13,439,325	$241,425	37,331	$1,612,719
Total	1,158,870		342,225,911	$3,476,610		**$41,067,109** -$3,476,610
Savings					**950,628**	***$37,590,499**

*Postage cost is not included in this estimate.

** Labor Hours calculated based upon photocopying/scanning at the rate of 6 pages per minute (labor hour savings $= \frac{342,225,911}{6\,x60}) = 950,627.50$)

TABLE 2--ESTIMATED CMS COST SAVING FOR QIOs PROCESSING PAPER PATIENT RECORDS

QIO Review Type	**5-Year Case Volume**	**Average Number of pages per Medical Record**	**Total Number of Pages per Review Type**	**QIO Labor Hours ****	**Estimated Total Cost for Scanning and Uploading by QIOs (Based on $0.10 per page)**
Hospital Discharge Appeal Review (Weichardt QOC)	159,343	408	65,011,944	180,589	$6,501,194
Fee for Service Non-coverage Review (BIPA Appeals)	171,239	247	42,296,033	117,489	$4,229,603
Medicare Advantage Non-coverage Review (Grijalva Appeals)	394,684	247	97,486,948	270,797	$9,748,695
Hospital Inpatient Short Stay Claims Review	197,000	226	44,522,000	123,672	$4,452,200
Hospital Inpatient DRG Claims Validation	156,129	509	79,469,661	220,749	$7,946,966
Other Focused Claims Review	80,475	167	13,439,325	37,331	$1,343,933
Total	1,158,870		342,225,911		**$34,222,591**
Savings				**950,628**	**$34,222,591**

*** Cost of scanning and uploading of received medical records does not include cost of paper.

TABLE 3. ONE- AND FIVE-YEAR ESTIMATED CMS COST SAVINGS AND BURDEN ESTIMATE

	Savings		**Burden (in hours)**	
	1 Year	**5 Years**	**1 Year**	**5 Years**
Total cost and burden savings for CMS	$14,362,618.08	$71,813,090.42	380,251	1,901,255

The BFCC–QIO contracts under the 12th scope of work currently have four task orders that are awarded on a staggered 5-year basis. Currently CMS has budgeted $95.8 million per year for each of the four BFCC–QIOs task orders, for an estimated 5-year cost of $479 million. We estimate that the costs of file transfer through photocopying and mailing, facsimile and in electronic formats would be a small fraction of the total operations budget of the QIOs. We believe that the changes we are adopting to the requirements governing reimbursement to providers, practitioners and institutions for submitting requested patient records to the QIO would also benefit providers, practitioners and institutions in fulfilling their responsibilities under § 476.78 (obligating providers and practitioners to, among other things, furnish records to QIOs) and § 480.111 (obligating institutions and practitioners to provide access, records and information to QIOs), by providing reimbursement for the submission of requested patient records to the QIOs in an electronic format.

Given our estimate, discussed in section IX.A.2.d. of this final rule that an appropriate employee can reasonably photocopy 6 pages of documents per minute and scan documents at the rate of 6 documents per minute, we estimate that the changes we are adopting would save providers and CMS a total of approximately 1.9 million labor hours over 5 years. We expect these proposed changes would also result in a positive environmental impact by avoiding printing, photocopying, faxing, scanning, and recycling about 342.2 million pages of medical records by providers and QIOs over 5 years.

We did not receive public comments on the methodologies used to calculate the reimbursement rates for electronic submission of patient records, submission of patient records via photocopying and mailing, or submission of patient records via facsimile. Since we did not receive comments on the methodologies used to calculate these rates, we continue to believe that the rates are reasonable, and that the cost savings we have calculated for the adopted changes are reasonable.

12. Effects of the Changes To Prepare for Implementation of Mandatory PRRB Electronic Filing

In section IX.B. of the preamble of this final rule, we are implementing the proposed changes regarding PRRB appeals. The burden associated with the requirements is the time and effort necessary to review instructions and register for the electronic submission system as well as the time and effort to gather, develop and submit various documents associated with a PRRB appeal. We also believe that requiring all parties involved in PRRB appeals to use OH CDMS would create efficiencies and reduce the burden and cost to external users in that, when a file or document is uploaded into the system and filed with the Board, the system simultaneously serves it on the opposing party. As a result, the system will eliminate the need to print documents and pay for postage for most submissions. Additionally, there is no material out-of-pocket direct cost or investment to utilize OH CDMS; parties do not need to purchase separate software. Finally, the required use of the system would also reduce the administrative burden on OH staff to enter data and scan correspondence, and will free up government resources to adjudicate cases and manage the docket. Similarly, it will enhance the PRRB's ability to strategically manage the PRRB's complex docket as it will provide better analytics for case management activities such as scheduling, jurisdictional and procedural reviews, and long-range docket planning. Last, the required use of the system would also reduce paper documents and the related costs associated with processing and securely storing the PRRB's records.

13. Effects of the Proposed Revisions of Medicare Bad Debt Policy

In section IX.C. of the preamble of this final rule, we are implementing the proposed clarifications and codification of certain longstanding Medicare bad debt reimbursement provisions and requirements for all Medicare providers, suppliers, and other entities eligible to receive Medicare payment for bad debt by revising 42 CFR 413.89, Bad debts, charity, and courtesy allowances. We are also implementing our proposal to codify our longstanding reasonable collection effort to require a Medicaid remittance advice (RA) for dual eligible beneficiaries. In the proposed rule, we sought suggestions from stakeholders regarding the best alternative documentation to the Medicaid RA that a provider could obtain and submit to Medicare to evidence the State's Medicare cost sharing liability (or absence thereof) in instances where the State does not process a Medicare crossover claim and issue a Medicaid RA for certain dual eligible beneficiaries. In addition, we are finalizing our proposal to recognize the new Accounting Standard Update—Topic 606 for revenue recognition and classification of Medicare bad debts. We also made a technical correction to the cross references in 42 CFR 412.622(b)(2)(i) and 42 CFR 417.536(g) to Medicare bad debt reimbursement policy. As a result of our proposed changes, there would be no costs to the Medicare Program and no increased burden placed upon providers, suppliers or other entities. In addition, there would be a savings to the Medicare Program by the reduction of appeal and litigation costs. Providers would benefit and realize a burden reduction with the finalization of a policy to accept alternative documentation to evidence a provider's reasonable collection effort for certain dual eligible beneficiaries, as doing so would serve an important public interest by allowing providers with cases currently pending before the PRRB an avenue for timely and cost-effective resolution, as well as an avenue for providers and contractors to resolve open cost reports containing these dual eligible crossover bad debt matters.

Comment: While some commenters were supportive of our efforts to clarify longstanding Medicare bad debt policies, many commenters expressed disagreement with proposals to codify some longstanding Medicare bad debt policies with retroactive effective dates. Commenters were generally supportive of our solicitation for suggestions to accept alternative documentation to the Medicaid RA for Medicare crossover bad debts to evidence a provider's reasonable collection effort for certain dual eligible beneficiaries. Some commenters suggested that a retroactive codification of some policies would create a burden and cause providers to re-submit prior cost reports. Other commenters submitted suggestions for the acceptance of alternative documentation to the Medicaid RA, asserting that it will provide a burden reduction to providers, including those with pending PRRB cases. Many commenters requested regulation text edits regarding to our proposal to adopt the Accounting Standard Update—Topic 606 for revenue recognition and classification of Medicare bad debts. Some commenters also inquired whether the PRM would also be updated.

Response: We appreciate commenters' support of our efforts to clarify longstanding Medicare bad debt policies. We believe the clarification and codification of many longstanding bad debt policies will benefit stakeholders when processing Medicare bad debt for reimbursement. Our acceptance of commenters' suggestions for alternative documentation to the Medicaid RA will allow providers an avenue for resolution of pending PRRB cases. We agree with some commenters' suggestions to further edit and clarify the regulation text proposals regarding the Accounting Standard Update—Topic 606 for revenue recognition and classification of Medicare bad debts. We plan to update the PRM to coincide with the policy clarifications to further assist providers with policy guidance.

After consideration of the public comments we received, we are finalizing our proposals to codify some of our longstanding Medicare bad debt policies as set forth in section IX.C. of this final rule. Some of the longstanding bad debt policy clarifications will be effective retroactively, while others will have effective dates for cost reporting periods beginning on or after October 1, 2020. We believe the retroactive effective dates of the policy clarifications and acceptance of alternative documentation to the Medicaid RA will serve to benefit providers with greater clarity and resolution of pending PRRB cases.

14. Effects of a Potential Market-Based MS–DRG Relative Weight Methodology

In section IV.P.4. of the preamble of this final rule, we finalizing the adoption of a market-based methodology for estimating the MS–DRG relative weights beginning in FY 2024, utilizing the median payer-specific negotiated charge information we are finalizing to collect on the Medicare cost report. We are finalizing our data collection proposal with modification to only collect the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations, rather than collecting both the median payer-specific negotiated charge by MS–DRG for payers that are MA organization and third party payers, as proposed. We note that in response to comments, we have increased the estimated total annual burden hours by 5 hours for this data collection requirement; 20 hours per hospital times 3,189 total hospitals equals 63,780 annual burden hours and $4,315,993 annually for all hospitals nationally. We refer readers to

section XI.B.11. of the preamble of this final rule for further analysis of this assessment.

We are applying a budget neutrality factor to ensure that the overall payment impact of any MS–DRG relative weight changes is budget neutral, as required by section 1886(d)(4)(C)(iii) of the Act and consistent with our current practice.

Once we have access to the payer-specific negotiated charge information at the MS–DRG level, we will be able to more precisely estimate the payment impact of adopting this market based MS–DRG relative weight methodology for payments beginning in FY 2024. However, to explore the potential impacts more generally, we conducted a literature review to compare the payment rates of Medicare FFS, MA organizations, and other commercial payers. As noted in section IV.P.2.b. of the preamble of the proposed rule and this final rule, Berenson et al.[531] surveyed senior hospital and health plan executives and found that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less. Respondents broadly identified three primary reasons for near-payment equivalence: Statutory and regulatory provisions that limit out-of-network payments to traditional Medicare rates, de facto budget constraints that MA plans face because of the need to compete with traditional Medicare and other MA plans, and a market equilibrium that permits relatively lower MA rates as long as commercial rates remain well above the traditional Medicare rates.

We next researched empirically based comparisons of Medicare FFS rates, MA organization rates, and rates of other commercial payers. Baker et al.[532] used data from Medicare and the Health Care Cost Institute (HCCI) to identify the prices paid for hospital services by FFS Medicare, MA plans, and commercial insurers in 2009 and 2012. They calculated the average price per admission, and its trend over time, in each of the three types of insurance for fixed baskets of hospital admissions across metropolitan areas. After accounting for differences in hospital networks, geographic areas, and case-mix between MA and FFS Medicare, they found that MA plans paid 5.6 percent less for hospital services compared to FFS Medicare. For the time period studied, the authors suggest that at least one channel through which MA plans paid lower prices was by obtaining greater discounts on types of FFS Medicare admissions that were known to have very short lengths-of-stay. They also found that the rates paid by commercial plans were much higher than those of either MA or FFS Medicare, and growing. At least some of this difference they indicated came from the much higher prices that commercial plans paid for profitable service lines.

Maeda and Nelson[533] also analyzed data from the HCCI in their research. They compared the hospital prices paid by MA organizations and commercial plans with Medicare FFS prices using 2013 claims from the HCCI. The HCCI claims were used to calculate hospital prices for private insurers, and Medicare's payment rules were used to estimate Medicare FFS prices. The authors focused on stays at acute care hospitals in metropolitan statistical areas (MSAs). They found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. The authors considered their results generally consistent with the Baker et al. study findings in that hospital payments by MA plans were much more similar to Medicare FFS levels than they were to commercial payment levels, although they noted that they used slightly different methods to calculate Medicare FFS prices.

In their study, Maeda and Nelson also examined whether the ratio of MA prices to FFS prices varied across DRGs to assess whether there were certain DRGs for which MA plans tended to pay more or less than FFS. They ranked the ratio of MA prices to FFS prices and adjusted for outlier payments. They found that there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS. For example, for the time period in question on average MA plans paid 129 percent more than FFS for rehabilitation stays (DRG 945), 33 percent more for depressive neuroses (DRG 881), and 27 percent more for stays related to psychoses (DRG 885). But MA plans paid an average of 9 percent less than FFS for stays related to pathological fractures (DRG 542) and wound debridement and skin graft (DRG 464) (see Online Appendix Table 5 from their study). The authors state these results suggest that there may be certain services where MA plans pay more than FFS, possibly because the FFS rate for those services is too low, but there may be other services where MA plans pay less than FFS, possibly because the FFS rate for those DRGs is too high.

As described previously, this body of research suggests that while the payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, there may be instances where those negotiated charges may reflect the relative hospital resources used within an MS–DRG differently than our current cost-based methodology. Payer-specific charges negotiated between hospitals and commercial payers are generally not as well-correlated with Medicare IPPS payment rates.

As previously noted, once we have access to the payer-specific negotiated charge information at the MS–DRG level, we can more precisely estimate the potential payment impact, which we intend to do in future rulemaking, prior to the FY 2024 effective date of the market-based MS–DRG relative weight methodology. As under the current methodology, the impact of any MS–DRG relative weight changes on an individual hospital would depend on the mix of services provided by that particular hospital.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section, we used data from the March 2020 update of the FY 2019 MedPAR file and the March 2020 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2020 update of the most recently available hospital cost report data (FYs 2017 and 2018) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2020 update of the FY 2019 MedPAR file, we simulated payments under the capital IPPS for FY 2020 and the payments for FY 2021 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2021 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable

[531] Berenson RA, Sunshine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. *Health Aff (Millwood).* 2015;34(8):1289–1295.

[532] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. *Health Aff (Millwood).* 2016;35(8):1444–1451.

[533] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? *The Journal of Health Care Organization, Provision, and Financing.* 2018;55(1–8).

changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this final rule, the update to the capital Federal rate is 1.1 percent for FY 2021.

- In addition to the FY 2021 update factor, the FY 2021 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9971 and an outlier adjustment factor of 0.9466.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this final rule to estimate the potential impact of the changes for FY 2021 on total capital payments per case, using a universe of 3,201 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2020 update of the FY 2019 MedPAR file, the March 2020 update to the PSF, and the most recent cost report data from the March 2020 update of HCRIS. In Table III, we present a comparison of estimated proposed total payments per case for FY 2020 and estimated total payments per case for FY 2021 based on the FY 2021 payment policies. Column 2 shows estimates of payments per case under our model for FY 2020. Column 3 shows estimates of payments per case under our model for FY 2021. Column 4 shows the total percentage change in payments from FY 2020 to FY 2021. The change represented in Column 4 includes the 1.1 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2021 are expected to increase as compared to capital payments per case in FY 2020. This expected increase overall is primarily due to the 1.1 percent update to the capital Federal rate for FY 2021, in conjunction with estimated changes in outlier payments and DSH payments. Under § 412.320, in order to receive capital DSH payments a hospital must be located in an urban area for payment purposes and have 100 or more beds. As discussed in section III.A.2. of the preamble of this final rule, there are counties that will become rural beginning October 1, 2020 based on our adoption of the revised OMB delineations, and therefore, hospitals in those areas (that have 100 or more beds) will no longer be eligible for capital DSH payments beginning in FY 2021. In general, regional variations in estimated capital payments per case in FY 2021 as compared to capital payments per case in FY 2020 are primarily due to changes in GAFs, and are generally consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these changes is an estimated 0.3 percent increase in capital payments per case from FY 2020 to FY 2021 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2021 as compared to FY 2020. Capital IPPS payments per case would increase by an estimated 0.3 percent for hospitals in urban areas while payments to hospitals in rural areas would increase by 0.6 percent in FY 2020 to FY 2021.

The comparisons by region show that the estimated changes in capital payments per case from FY 2020 to FY 2021 would increase in certain urban areas, ranging from a 0.6 percent increase for the East South Central region to a 1.0 percent increase for the New England region. We estimate a decrease for certain other urban regions ranging from 0.1 percent for the South Atlantic region to 0.8 percent for the Mountain region for the capital payments per case from FY 2020 to FY 2021. We estimate no change for the East North Central region for the capital payments per case from FY 2020 to FY 2021. However, nearly all rural regions are expected to increase in capital payments per case from FY 2020 to FY 2021, ranging from 0.1 percent for the West North Central to a 1.3 percent increase for the East North Central rural region. We estimate no change in capital payment per case from FY 2020 to FY 2021 for the South Atlantic rural region. These regional differences are primarily due to the changes in the GAFs and estimated changes in outlier and DSH payments.

All Hospital ownership types are expected to experience an increase in capital payments per case from FY 2020 to FY 2021. Voluntary hospitals are expected to experience an increase in capital IPPS payments of 0.2 percent, and the projected increase in capital payments for Proprietary hospitals is estimated to be 0.3 percent. We also estimate an increase in capital payments per case from FY 2020 to FY 2021 for the Government type hospital to be 0.5 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2021. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this final rule for FY 2021, we show the average capital payments per case for reclassified hospitals for FY 2021. Urban reclassified hospitals are expected to experience a decrease in capital payments of 0.3 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 0.7 percent. The estimated percentage increase for rural reclassified hospitals is 0.6 percent, and for rural nonreclassified hospitals, the estimated percentage increase in capital payments is 0.5 percent.

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TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2020 PAYMENTS COMPARED TO FINAL FY 2021 PAYMENTS]

	Number of hospitals	Average FY 2020 payments/ case	Final Average FY 2021 payments/ case	Change
All hospitals	3,201	976	979	0.3
By Geographic Location:				
Urban Hospitals	2,462	1,009	1,012	0.3
Rural areas	739	667	671	0.6
Bed Size (Urban)				
0-99 beds	635	813	814	0.1
100-199 beds	756	855	858	0.4
200-299 beds	426	932	935	0.3
300-499 beds	422	1,012	1,014	0.2
500 or more beds	223	1,211	1,215	0.3
Bed Size (Rural)				
0-49 beds	312	567	570	0.5
50-99 beds	254	622	624	0.3
100-149 beds	95	661	664	0.5
150-199 beds	39	725	731	0.8
200 or more beds	39	787	793	0.8
By Region:				
Urban by Region				
New England	112	1,090	1,101	1.0
Middle Atlantic	305	1,113	1,121	0.7
South Atlantic	402	887	886	-0.1
East North Central	381	962	962	0.0
East South Central	144	857	862	0.6
West North Central	160	995	992	-0.3
West South Central	364	923	929	0.7
Mountain	172	1,032	1,024	-0.8
Pacific	372	1,293	1,302	0.7
Rural by Region				
New England	19	928	935	0.8
Middle Atlantic	50	643	647	0.6
South Atlantic	114	620	620	0.0
East North Central	114	668	677	1.3
East South Central	144	626	629	0.5
West North Central	89	697	698	0.1
West South Central	136	597	599	0.3
Mountain	49	758	762	0.5
Pacific	24	862	872	1.2

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2020 PAYMENTS COMPARED TO FINAL FY 2021 PAYMENTS]

	Number of hospitals	Average FY 2020 payments/ case	Final Average FY 2021 payments/ case	Change
By Payment Classification:				
Urban hospitals	2,049	998	1,005	0.7
Rural areas	1,152	933	929	-0.4
Teaching Status:				
Non-teaching	2,037	818	820	0.2
Fewer than 100 Residents	907	931	934	0.3
100 or more Residents	257	1,349	1,356	0.5
Urban DSH:				
Non-DSH	505	901	902	0.1
100 or more beds	1,289	1,025	1,032	0.7
Less than 100 beds	351	739	741	0.3
Rural DSH:				
Sole Community (SCH/EACH)	259	687	690	0.4
Referral Center (RRC/EACH)	545	980	976	-0.4
100 or more beds	36	979	949	-3.1
Less than 100 beds	216	556	559	0.5
Urban teaching and DSH:				
Both teaching and DSH	739	1,092	1,102	0.9
Teaching and no DSH	74	951	957	0.6
No teaching and DSH	901	867	872	0.6
No teaching and no DSH	335	869	871	0.2
Special Hospital Types:				
Non special status hospitals	168	851	834	-2.0
RRC/EACH	483	1,010	1,005	-0.5
SCH/EACH	304	758	761	0.4
Medicare-dependent hospitals (MDH)	145	593	593	0.0
SCH, RRC and EACH	149	799	803	0.5
MDH, RRC and EACH	25	664	664	0.0
Type of Ownership:				
Voluntary	1,885	988	990	0.2
Proprietary	827	886	889	0.3
Government	488	1,029	1,034	0.5
Medicare Utilization as a Percent of Inpatient Days:				
0-25	641	1,115	1,119	0.4
25-50	2,114	966	969	0.3
50-65	373	794	796	0.3
Over 65	49	594	593	-0.2
2021 Reclassifications by the Medicare Classification Review Board:				
All Reclassified Hospitals	900	957	956	-0.1
All Nonreclassified Hospitals	2,301	987	992	0.5
Urban Hospitals Reclassified	722	1,013	1,010	-0.3
Urban Nonreclassified Hospitals	1,752	1,005	1,012	0.7
Rural Hospitals Reclassified Full Year	309	687	691	0.6
Rural Nonreclassified Hospitals Full Year	418	637	640	0.5
All Section 401 Reclassified Hospitals	467	1,030	1,022	-0.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	657	660	0.5

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J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2021. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2021, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this final rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 363 LTCHs included in this impact analysis. We note that, although there are currently approximately 373 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2021 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this final rule. Moreover, in the claims data used for this final rule, 3 of these 363 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.) In the

impact analysis, we used the payment rate, factors, and policies presented in this final rule, the 2.3 percent annual update to the LTCH PPS standard Federal payment rate, the permanent one-time budget neutrality adjustment factor for the estimated cost of eliminating the 25-percent threshold policy in FY 2021 as discussed in section VII.D. of the preamble of this final rule, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values, labor-related share, and changes to the geographic labor-market area designations, and the 5-percent cap transition policy, and the best available claims and CCR data to estimate the change in payments for FY 2021.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019. For FY 2021, we expected no site neutral payment rate cases would still be eligible for the transitional payment method since it only applies to those site neutral payment rate cases whose discharges occur during a LTCH's cost reporting period that begins before October 1, 2019. Site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1).

Based on the best available data for the 363 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2021 will decrease by approximately 1.1 percent (or approximately $40 million) based on the rates and factors presented in section VII. of the preamble and section V. of the Addendum to this final rule.

The applicability of this transitional payment method for site neutral payment rate cases is dependent upon both the discharge date of the case and the start date of the LTCH's FY 2020 cost reporting period. The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2019 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the LTCH PPS standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). There are LTCHs that have a cost reporting period that began during FY 2019 that includes discharges that occur during Federal FY 2020. For example, an LTCH with a January 1, 2019 through December 31, 2019 cost reporting period had 3 months of discharges that occurred during Federal FY 2020 (that is, discharges that occur from October 1, 2019 through December 31, 2019).

Therefore, when estimating FY 2020 LTCH PPS payments for site neutral payment rate cases for this impact analysis, because the statute specifies that the site neutral payment rate effective date for a given LTCH is based on the date that the LTCH's cost reporting period begins during FY 2020, we included an adjustment to account for this rolling effective date, consistent with the general approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 49831). This approach accounts for the fact that site neutral payment rate cases in FY 2020 that are in an LTCH's cost reporting period that begins before October 1, 2019 continue to be paid under the transitional payment method until the start of the LTCH's first cost reporting period beginning on or after October 1, 2019. Site neutral payment rate cases whose discharges from LTCHs occurring during an LTCH's cost reporting period that begins on or after October 1, 2019 will no longer be paid under the transitional payment method and will instead be paid the site neutral payment rate amount as determined under § 412.522(c)(1).

For purposes of this impact analysis, to estimate total FY 2020 LTCH PPS payments for site neutral payment rate cases, as we proposed, we used the same general approach as was used in the FY 2016 IPPS/LTCH PPS proposed rule with modifications to account for the rolling end date to the transitional blended payment rate in FY 2020 instead of the rolling effective date for implementation of the transitional site neutral payment rate in FY 2016. (We note, this is the same approach as was used in the FY 2018 IPPS/LTCH PPS proposed and final rules, which was prior to the extension of the transitional blended payment for LTCH cost reporting periods beginning in FY 2018 and FY 2019 provided by the provisions of section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123). In summary, under this approach, we grouped LTCHs based on the quarter their cost reporting periods will begin during FY 2020. For example, LTCHs with cost reporting periods that begin during October through December 2020 begin during the first quarter of FY 2020. For LTCHs grouped in each quarter of FY 2020, we modeled those LTCHs' estimated FY 2020 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group will continue to be paid the transitional payment method for the site neutral payment rate cases.

For purposes of this estimate, then, we assume the cost reporting period is the same for all LTCHs in each of the quarterly groups and that this cost reporting period begins on the first day of that quarter. (For example, the first group consists of 38 LTCHs whose cost reporting period begins in the first quarter of FY 2020 so that, for purposes of this estimate, we assume all 38 LTCHs began their FY 2020 cost reporting period on October 1, 2019.) Second, we estimated the proportion of FY 2020 site neutral payment rate cases in each of the quarterly groups, and we then assume this proportion is applicable for all four quarters of FY 2020. (For example, as discussed in more detail later in this section, we estimate the first quarter group will discharge 7.9 percent of all FY 2020 site neutral payment rate cases; and therefore, we estimate that group of LTCHs will discharge 7.9 percent of all FY 2020 site neutral payment rate cases in each quarter of FY 2020.) Then, we modeled estimated FY 2020 payments on a quarterly basis under the LTCH PPS standard Federal payment rate based on the assumptions described previously. We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2020 payments.

For purposes of this impact analysis, to estimate total FY 2021 LTCH PPS payments for site neutral payment rate cases, the transitional blended payment rate was not applied to such cases because all discharges in FY 2021 are either in the LTCH's cost reporting period that began during FY 2020 or in the LTCH's cost reporting period that will begin during FY 2021. Site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1).

Based on the fiscal year begin date information in the March 2020 update of the provider specific file (PSF) and the LTCH claims from the March 2020 update of the FY 2019 MedPAR files for the 363 LTCHs in our database used for this final rule, we found the following: 7.9 percent of site neutral payment rate cases are from 38 LTCHs whose cost reporting periods began during the first quarter of FY 2020; 19.8 percent of site neutral payment rate cases are from 81 LTCHs whose cost reporting periods will begin in the second quarter of FY 2020; 9.4 percent of site neutral payment rate cases are from 48 LTCHs whose cost reporting periods will begin in the third quarter of FY 2020; and 62.9 percent of site neutral payment rate cases are from 193 LTCHs whose cost reporting periods will begin in the fourth quarter of FY 2020. (We note, three of the 363 LTCHs in our database used for this final rule did not have any site neutral payment rate cases.) Therefore, the following percentages apply in the approach described previously:

- *First Quarter FY 2020:* 7.9 percent of site neutral payment rate cases (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period began in the first quarter of FY 2020) are no longer eligible for the transitional blended payment method, while the remaining 92.1 percent of site neutral payment rate discharges are eligible to be paid under the transitional payment method.
- *Second Quarter FY 2020:* 27.7 percent of site neutral payment rate second quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period that begins in the first or second quarter of FY 2020) are no longer

eligible for the transitional blended payment method, while the remaining 72.3 percent of site neutral payment rate second quarter discharges are eligible to be paid under the transitional payment method.

- *Third Quarter FY 2020:* 37.1 percent of site neutral payment rate third quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period that begins in the first, second, or third quarter of FY 2020) are no longer eligible for the transitional blended payment method while the remaining 62.9 percent of site neutral payment rate third quarter discharges are eligible to be paid under the transitional payment method.
- *Fourth Quarter FY 2021:* 100.0 percent of site neutral payment rate fourth quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period that begins in the first, second, third, or fourth quarter of FY 2020) are no longer eligible for the transitional blended payment method.

Based on the FY 2019 LTCH cases that were used for the analysis in this final rule, approximately 25 percent of those cases were classified as site neutral payment rate cases (that is, 25 percent of LTCH cases did not meet the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2021 will not change significantly from the most recent historical data. Taking into account the transitional blended payment rate and other changes that will apply to the site neutral payment rate cases in FY 2021, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 24 percent (or approximately $114 million). We note, we estimate payments to site neutral payment rate cases in FY 2021 represent approximately 10 percent of estimated aggregate FY 2021 LTCH PPS payments.

Based on the FY 2019 LTCH cases that were used for the analysis in this final rule, approximately 75 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2021, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2021 will increase approximately 2.2 percent (or approximately $74 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2021 is primarily due to the 2.3 percent annual update to the LTCH PPS standard Federal payment rate for FY 2021.

Based on the 363 LTCHs that were represented in the FY 2019 LTCH cases that were used for the analyses in this final rule presented in this Appendix, we estimate that aggregate FY 2020 LTCH PPS payments will be approximately $3.774 billion, as compared to estimated aggregate FY 2021 LTCH PPS payments of approximately $3.733 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $40 million. As discussed earlier, this estimated decrease in payments is primarily due to the rolling end to the statutory transitional blended payment rate for site neutral payment rate cases. We also note that the estimated $40 million decrease in LTCH PPS payments in FY 2021 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2020 is $42,677.64. For FY 2021, we are establishing an LTCH PPS standard Federal payment rate of $43,755.34 which reflects the 2.3 percent annual update to the LTCH PPS standard Federal payment rate, the incremental change in the one-time budget neutrality adjustment factor of 0.991249 for eliminating the 25-percent threshold policy in FY 2021 as discussed in section VII.D. of the preamble of this final rule, and the budget neutrality factor for general updates to the area wage level adjustment of 1.0016837 (discussed in section V.B.6. of the Addendum to this final rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $42,899.90. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the FY 2021 LTCH PPS standard Federal payment rate are applied to the FY 2020 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xvi) (that is, $42,677.64).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update of 2.3 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.3 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021, on average, for all LTCHs (Column 6). The estimated increase of 2.3 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. However, for most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases still rounds to approximately 2.3 percent, the same as the annual update for FY 2021.

For FY 2021, we are updating the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2017 which is the same data used for the FY 2021 IPPS wage index), the labor-related share of 68.1 for FY 2021, based on the most recent available data (IGI's second quarter 2020 forecast) on the relative importance of the labor-related share of operating and capital costs of the 2017-based LTCH market basket, and the changes to the labor market areas based on the revisions to the CBSA delineations. We also are applying an area wage level budget neutrality factor of 1.0016837 to ensure that the changes to the area wage level adjustment, including the 5-percent cap transition policy, would not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease slightly from FY 2020 to FY 2021. Based on the FY 2019 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2020 high cost outlier threshold of $26,778 (as established in the FY 2020 IPPS/LTCH PPS final rule) would result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2020 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 8.005 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2020. Combined with our estimate that FY 2021 high cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2021, this will result in an estimated decrease in high cost outlier payments of approximately 0.03 percent between FY 2020 and FY 2021. We note that, consistent with past practice, in calculating these estimated high cost outlier payments, we increased estimated costs by an inflation factor of 4.3 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2021.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2021 by comparing estimated FY 2020 LTCH PPS payments to estimated FY 2021 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this final rule, based on the most recent available data, we believe that the provisions of this final rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

Comment: Several commenters expressed support for the proposed LTCH PPS standard Federal payment rate and the estimated increase in payments for LTCH PPS standard Federal payment rate cases.

Response: We thank the commenters for their support.

Comment: Some commenters objected that total LTCH PPS payments are estimated to decrease.

Response: As discussed previously and in the proposed rule, the estimated decrease in

LTCH PPS payments is largely due to the statutory rolling end of the blended payment rate. While we understand commenter's concerns, we believe that our estimate is correct and appropriately reflects the statute.

Comment: As they have since its inception, several commenters opposed the application of the site neutral payment rate. Some commenters also requested CMS revise or expand the criteria for exclusion from the site neutral payment rate.

Response: As we have stated since its inception, the application of and criteria for exclusion from the site neutral payment rate is statutory. CMS therefore lacks the authority to do as these commenters request. (We note however that under section 3711(b)(2) of the CARES Act, Pub. L. 116–136, all LTCH cases admitted during the COVID–19 public health emergency period will be paid the relatively higher LTCH PPS standard Federal rate.)

Comment: Multiple commenters stated their belief that cases paid at the site neutral payment rate will continue to be underpaid as those cases, according to commenters, have on average higher levels of clinical complexity and costs that significantly exceed IPPS-level reimbursement. These commenters acknowledged that CMS is unable to change this policy but request that CMS take into consideration the costs of site neutral payment rate cases when proposing any future changes to the LTCH PPS.

A commenter stated that since FY 2019 site neutral payment rate cases have seen a significant drop in reimbursement as a result of the end of the transitional blended payment rate. The commenter stated that the payment-to-cost ratio for site neutral payment rate cases without the blended payment rate will be 45 percent and treatment costs for these cases are comparable to LTCH PPS standard Federal payment rate cases as these site neutral cases have significant comorbidities which make it difficult to discharge them to lower levels of care. They also stated that their site neutral payment rate cases are almost three times costlier than IPPS cases with fewer than three ICU days.

A commenter acknowledged that the number of site neutral payment rate cases have dropped to 25 percent of total LTCH PPS cases in FY 2019. Because site neutral payment rate cases will longer receive the transitional blended payment rate in the FY 2021, the commenter believes this will lead to a continued decrease in the overall LTCH case volume.

Response: FY 2019 LTCH claims data are currently the best available data, and as noted previously, LTCH site neutral payment rate cases discharged during FY 2019 were partially paid the blended payment rate under the rolling end of the statutory transitional period. Due to the end of that transitional period for site neutral payment rate cases we continue to expect that costs and resource use for cases paid at the site neutral payment rate will likely be lower on average as compared to cases paid both prior to the implementation of the site neutral payment and during the transitional period and would continue to more closely resemble the costs and resource use for IPPS cases assigned to the same MS–DRG. We refer readers to 84 FR 42647 through 42648 for more information on our responses to these comments. We acknowledge commenters' concerns about the costs of treating site neutral cases, however, as noted by some commenters and discussed previously, the site neutral payment rate is a statutory requirement. We will consider the costs of site neutral payment rate cases as appropriate in future rulemaking.

Comment: Some commenters stated appreciation for the quick actions of CMS in its response to the COVID–19 pandemic and LTCH PPS policy changes, specifically CMS' implementation of section 3711(b) of the CARES Act which provides for a waiver of the site neutral payment rate for discharges that do not meet the LTCH patient criteria during the PHE period. These commenters expressed concern that the COVID–19 pandemic would affect relevant data used to determine payment rates for site neutral and LTCH PPS standard Federal payment rate cases and urged CMS to carefully consider these potential data distortions in collaboration with stakeholders in advance of rulemaking for FY 2022 and subsequent years. One commenter recommended CMS revise the estimated decrease in total LTCH PPS payments to an increase of 3.0 percent or more to help LTCHs meet the needs of COVID–19 patients.

Response: We appreciate the comments in regard to CMS' response to the COVID–19 pandemic and LTCH PPS payment policy. We understand the concerns expressed by commenters related to data used for future LTCH PPS payments and will take them in to account for future rulemaking. We recognize the impact that the COVID–19 PHE is having on all providers, which is why we have issued waivers and flexibilities to ease burden and allow providers to respond effectively during the COVID–19 PHE. Under section 3711(b)(2) of the CARES Act, Public Law 116–136, all LTCH cases admitted during the COVID–19 public health emergency period will be paid the relatively higher LTCH PPS standard Federal payment rate. As discussed previously, we project that payments to LTCH PPS standard Federal payment rate cases in FY 2021 will increase approximately 2.2 percent. We also note that our projected 1.1 percent decrease in total LTCH PPS payments does not account for the provisions of section 3711(b)(2) of the CARES Act if the PHE extends into FY 2021.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 1.7 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2019 data for the 18 rural LTCHs (out of 363 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable HCO payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J.2. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2021 of approximately $40 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $74 million and the projected decrease in payments to site neutral payment rate cases of approximately $114 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016. (We note that these calculations are based on unrounded numbers and thus may not sum as expected.)

As discussed in section V.D. of the Addendum to this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG.

While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2021 LTCH PPS payments (that is, FY 2019 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2021, it is necessary to estimate payments per discharge for FY 2020 using the rates, factors, and the policies established in the FY 2020 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2021 using the rates, factors, and the policies in this FY 2021 IPPS/LTCH PPS final rule (as discussed in section VII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2020 and FY 2021 payments on a case-by-case basis using historical LTCH claims from the FY 2019 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2019 MedPAR files. For modeling FY 2020 LTCH PPS payments, we used the FY 2020 standard Federal payment rate of $42,677.64 (or $41,844.90 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the FY 2021 LTCH PPS standard Federal payment rate, we used the FY 2021 standard Federal payment rate of $43,755.34 (or $42,899.90 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2020 LTCH PPS payments, we used the current FY 2020 labor-related share (66.3 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2020 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2020 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $26,778 (as reflected in the FY 2020 IPPS/LTCH PPS final rule), and the FY 2020 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2020 nonlabor-related share (33.7 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2021 LTCH PPS payments, we used the FY 2021 LTCH PPS labor-related share (68.1 percent), the FY 2021 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website), the FY 2021 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,195 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2021 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2021 nonlabor-related share (31.9 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 2.0 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2020, and an inflation factor of 4.3 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2021.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2020 to FY 2021 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2020 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2021 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2020 to FY 2021 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for changes due to the changes to the area wage level adjustment (that is, the updated hospital wage data, labor-related share, and the to the geographic labor-market area designations, including the 5-percent cap transition policy), and the application of the corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 (Column 4) to FY 2021 (Column 5) for all changes.

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TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2021 (ESTIMATED FY 2020 PAYMENTS COMPARED TO ESTIMATED FY 2021 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2020 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	360	68,764	48,060	49,134	2.3	0.0	2.2
BY LOCATION:							
RURAL	18	2,818	38,625	39,272	2.4	-0.4	1.7
URBAN	342	65,946	48,464	49,555	2.3	0.0	2.3
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	1,788	45,020	45,996	2.3	-0.2	2.2
OCT. 1983 - SEPT. 1993	40	8,883	53,366	54,642	2.2	0.2	2.4
OCT. 1993 - SEPT. 2002	145	28,209	47,072	48,092	2.3	-0.1	2.2
AFTER OCTOBER 2002	165	29,884	47,598	48,667	2.3	0.0	2.2
BY OWNERSHIP TYPE:							
VOLUNTARY	60	8,517	50,497	51,682	2.3	-0.1	2.3
PROPRIETARY	290	59,088	47,503	48,553	2.3	0.0	2.2
GOVERNMENT	10	1,159	58,576	60,004	2.2	0.0	2.4
BY REGION:							
NEW ENGLAND	10	2,374	43,233	44,024	2.3	-0.6	1.8
MIDDLE ATLANTIC	23	5,310	55,837	57,061	2.2	-0.2	2.2
SOUTH ATLANTIC	62	13,107	47,486	48,495	2.3	-0.1	2.1
EAST NORTH CENTRAL	55	10,260	47,002	48,052	2.3	0.0	2.2
EAST SOUTH CENTRAL	31	5,784	43,395	44,239	2.3	-0.3	1.9
WEST NORTH CENTRAL	22	4,152	45,579	46,459	2.3	-0.5	1.9

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2020 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
WEST SOUTH CENTRAL	105	17,198	43,207	44,180	2.3	0.1	2.3
MOUNTAIN	29	3,371	49,303	50,266	2.3	-0.4	2.0
PACIFIC	23	7,208	62,645	64,433	2.1	0.6	2.9
BY BED SIZE:							
BEDS: 0-24	22	2,243	46,284	47,175	2.3	-0.6	1.9
BEDS: 25-49	166	23,651	45,086	46,053	2.3	-0.1	2.1
BEDS: 50-74	97	19,086	48,437	49,536	2.3	0.0	2.3
BEDS: 75-124	48	13,852	52,084	53,290	2.2	0.0	2.3
BEDS: 125-199	19	5,977	49,810	50,960	2.2	0.0	2.3
BEDS: 200+	8	3,955	48,301	49,405	2.2	0.1	2.3

[1] Estimated FY 2021 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for changes due to the changes to the area wage level adjustment under § 412.525(c) (that is, updated hospital wage data, the labor related share, the to the geographic labor-market area designations, and the 5-percent cap transition, as discussed in section V.B. of the Addendum to this final rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 (shown in Column 4) to FY 2021 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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d. Results

Based on the FY 2019 LTCH cases (from 363 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate

cases are projected to increase 2.2 percent, on average, for all LTCHs from FY 2020 to FY 2021 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 2.2 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2021 LTCH PPS payments (using the final payment rates and factors discussed in this final rule) to estimated FY 2020 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are updating the LTCH PPS standard Federal payment rate for FY 2021 by 2.3 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. In addition, we are applying the incremental change in the one-time budget neutrality adjustment factor of 0.991249 for the cost of eliminating the 25-percent threshold policy in FY 2021 as discussed in section VII.D. of the preamble of this final rule. Consistent with § 412.523(d)(4), we also are applying a budget neutrality factor for changes to the area wage level adjustment of 1.0016837 (discussed in section V.B.6. of the Addendum to this final rule), based on the best available data at this time, to ensure that any changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 2.3 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.3 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2020 to FY 2021. We note our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using a methodology that is not entirely affected by the update to the LTCH PPS standard Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may differ slightly from 2.3 percent due to the annual update to the LTCH PPS standard Federal payment rate for FY 2021.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for all hospitals is 2.2 percent. The projected increase for urban hospitals is 2.3 percent for urban hospitals, while the projected increase for rural hospitals is 1.7 percent. This smaller than average projected increase for rural LTCHs is primarily due to the changes to the area wage adjustment, including the changes to the labor market areas.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 43 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to both experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 of 2.2 percent. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are projected to experience the largest percent increase, 2.4 percent, in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 2.2 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 17 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary and proprietary LTCHs are each expected to experience an increase of 2.3 percent and 2.2 percent in payments to LTCH PPS standard Federal payment rate cases, respectively. Government owned and operated LTCHs, meanwhile, are expected to experience a 2.4 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2021 are projected to increase across all census regions. LTCHs located in the Pacific region are projected to experience the largest increase at 2.9 percent. The remaining regions are projected to experience an increase in payments in the range of 1.8 to 2.3 percent. These regional variations are primarily due to the changes to the area wage adjustment, including the changes to the labor market areas.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 0–24 beds will experience the smallest increase in payments for LTCH PPS standard Federal payment rate cases, 1.9 percent. LTCHs with 50–74 beds, 75–124 beds, 125–199 beds, and with 200 or more beds, will all experience the largest increase in payments for LTCH PPS standard Federal payment rate cases of 2.3 percent. LTCHs with 25–49 beds are projected to experience a 2.1 percent increase in payments.

5. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2021 relative to FY 2020 of approximately $74 million (or approximately 2.2 percent) for the 363 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2021 relative to FY 2020 of approximately $114 million (or approximately −24 percent) for the 363 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2021 represent approximately 10 percent of total estimated FY 2021 LTCH PPS payments.) Therefore, we project that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2021 relative to FY 2020 of approximately $40 million (or approximately −1.1 percent) for the 363 LTCHs in our database.

6. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this final rule, we are finalizing our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2022 payment determination and subsequent years.

In this final rule, we are finalizing our proposed reporting, submission, and public

display requirements for eCQMs, including policies to: (1) Progressively increase the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report: (a) Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination for each of the four self-selected eCQMs; (b) three quarters of data for the CY 2022 reporting period/FY 2024 payment determination for three self-selected eCQMs and the Safe Use of Opioids eCQM; and (c) four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years, while continuing to allow hospitals to report: (i) Three self-selected eCQMs, and (ii) the Safe Use of Opioids eCQM; and (2) begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. The Hospital IQR Program eCQM-related proposals being finalized are in alignment with proposals that we are finalizing under the Promoting Interoperability Program. We are also finalizing our proposal to expand the requirement to use EHR technology certified to the 2015 Edition for submitting data on not only the previously finalized Hybrid Hospital-Wide Readmission measure, but all hybrid measures in the Hospital IQR Program. While we believe there would be no change to the information collection burden estimate due to public display of eCQM data, we acknowledge that there is other burden associated with this provision. For example, there is burden associated with the optional reviewing of hospital-specific reports during the public reporting preview. However, we believe this burden is nominal because hospitals already review these reports with respect to other types of measures for the Hospital IQR Program.

We also are finalizing several proposed changes to streamline validation processes under the Hospital IQR Program. We will: (1) Require the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allow the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive starting with validation affecting the FY 2024 payment determination; (2) combine the validation processes for chart-abstracted measures and eCQMs for validation affecting the FY 2024 payment determination and subsequent years by: (a) Aligning data submission quarters; (b) combining hospital selection, including: (i) Reducing the pool of hospitals randomly selected for chart-abstracted measure validation; and (ii) integrating and applying targeting criteria for eCQM validation; (c) removing previous exclusion criteria; and (d) combining scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero; and (3) formalize the process for conducting educational reviews beginning with eCQM validation affecting the FY 2023 payment determination in alignment with current processes for providing feedback for chart-abstracted validation results.

We estimate that the policies finalized in this final rule will result in an increase of 6,533 hours (6,660 − 67 hours) for 3,300 IPPS hospitals across a 4-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination. The total cost increase associated with these policies is approximately $253,480 (6,533 hours × $38.80) (which also reflects use of an updated hourly wage rate as previously discussed). We refer readers to section XI.B.7. of the preamble of this final rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital IQR Program.

With regard to our finalized policy to combine the hospital selection process, including the reduction of the pool of hospitals randomly selected for chart-abstracted measure validation from 400 hospitals to up to 200 hospitals, while we expect no change to the information collection burden for the Hospital IQR Program as discussed in section XI.B.7.b. of the preamble of this final rule because we directly reimburse hospitals for medical records, we believe there may be other cost savings beyond information collection burden due to 200 fewer hospitals being selected for Hospital IQR Program validation each year.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of this Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

A number of commenters expressed concern about an increase in burden related to our eCQM related proposals to increase the number of required reporting quarters for eCQM data and our proposal to begin publicly reporting eCQM data.

We believe the long-term benefits associated with reporting a full year of electronic data will outweigh the burdens and that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality information for patients and providers. We stated our intention in the FY 2018 IPPS/LTCH PPS final rule to gradually transition toward more robust eCQM reporting (82 FR 38356). We reiterated this stated goal to incrementally increase the use of EHR data for quality measurement in a subsequent final rule (84 FR 42502). We believe that taking an incremental approach to increasing eCQM reporting over a 3-year period will help to ease the burdens associated with reporting larger amounts of data and will provide hospitals and vendors with additional time to plan and sufficiently allocate resources for more robust eCQM reporting. We also believe the increase in reporting quarters does not represent a significant increase in burden beyond the existing requirement to report one quarter of eCQM data. Once the eCQM updates are implemented in hospital EHRs, reporting an additional quarter of data should not require the same level of effort as reporting one initial quarter of data because hospitals should not need to update the eCQM specifications each quarter. Thus, we do not expect hospitals to experience a significant amount of added burden reporting three additional quarters of data over a 3-year period. The data submission deadline for eCQM data under the Hospital IQR Program, regardless of how many quarters of data are required to be reported for a given calendar year, will continue to be the end of 2 months following the close of the respective calendar year. There is no additional information collection burden associated with our proposal to publically reporting eCQM data, however we acknowledge that there are other types of burden associated with this proposal. For example, there is burden associated with the optional reviewing of hospital-specific reports during the public reporting preview period; however, we believe this burden is nominal because hospitals already review these reports with respect to other types of measures for the Hospital IQR Program.

We agree with the majority of commenters who expressed that the finalization of the validation proposals would be less burdensome overall. Combining and aligning the hospital pool for validation between the programs would reduce burden by 400 hospitals per year starting with validation affecting the FY 2024 payment determination. This is supported by the majority of comments that we received in response to this proposal, which indicate that most hospitals believe that the combined process will be less burdensome. In addition, our proposal to reduce the overall number of hospitals selected for validation from 800 to up to 400, further reduces the overall validation burden.

For a detailed discussion of comments we received on the information collection burden associated with the finalization of these proposals, please see section VIII.A.10 of the preamble of this final rule. We believe the finalization of these proposals effectively balances the burdens associated with increased reporting of eCQM data and the benefits of providing that quality data to patients and consumers.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this final rule, we finalize our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section VIII.B.4. of the preamble of this final rule, we adopt refined versions of two existing measures: The Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure, beginning with the FY 2023

program year. As explained in section XI.B.8. of the preamble of this final rule, we do not anticipate any change in burden hours on the PCHs associated with our finalized policy to refine the CAUTI and CLABSI measures beginning with the FY 2023 program year because there are no changes to the data submission requirements for CAUTI and CLABSI.

We received no comments in response to the effects of requirements section specifically discussed above.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

We did not propose any policies and, therefore, are not finalizing any policies in this final rule for the LTCH QRP.

N. Effects of Proposed Requirements Regarding the Promoting Interoperability Programs

In section VIII.D. of the preamble of this final rule, we finalize our proposed requirements for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs. Specifically, we are finalizing the following proposed changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; (3) to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; (4) to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a 3-year period. Specifically, we will require: (a) 2 self-selected calendar quarters of data for the CY 2021 reporting period; (b) 3 self-selected calendar quarters of data for the CY 2022 reporting period; and (c) 4 calendar quarters of data beginning with the CY 2023 reporting period, where the submission period for the Medicare Promoting Interoperability Program will be the 2 months following the close of the respective calendar year; (5) to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021 on the *Hospital Compare* and/or *data.medicare.gov* websites or successor websites; (6) to correct errors and amend regulation text under § 495.104(c)(5)(viii)(B) through (D) regarding transition factors under section 1886(n)(2)(E)(i) for the incentive payments for Puerto Rico eligible hospitals; and (7) to correct errors and amend regulation text under § 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) for regulatory citations for the ONC certification criteria. We are amending our regulations as necessary to incorporate these changes. For the EHR reporting period in CY 2021, the provisions summarized in this section are mainly continuations of existing policies. However, two updated instances of a previous miscalculation and an updated Bureau of Labor Statistics wage rate will result in both a minor reduction of program burden hours (−44) as well as a small increase in total cost (+$24,024) for CY 2021.

We did not receive individual comments in response to the numerical impacts specifically discussed above, therefore, we are finalizing our impacts as proposed without modification. For a complete, detailed discussion of comments we received on the Promoting Interoperability Program's policy proposals, please see section VIII.D. of the preamble of this final rule.

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the final policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Implementation of Revised Labor Market Area Delineations

As discussed in section III.A.2. of the preamble of this final rule, the wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On September 14, 2018, OMB issued OMB Bulletin No. 18–04. While OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, under the revised OMB delineations, there are some new CBSAs, urban counties that become rural, rural counties that become urban, and existing CBSAs that are split apart. In addition, the revised OMB delineations will affect various hospital reclassifications, the out-migration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act.

We considered whether we should finalize the implementation of the revised OMB delineations as described in OMB Bulletin No. 18–04, beginning with the FY 2021 IPPS wage index, or whether we should wait to implement any further changes to the hospital labor market areas until OMB issues revisions to the statistical areas based on the results of the upcoming decennial census. We believe it is important for the IPPS to use updated labor market area delineations as soon as reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Furthermore, we believe that using the updated delineations in OMB Bulletin No. 18–04 will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, we decided not to wait until OMB issues revisions to the statistical areas based on the results of the upcoming decennial census, but are finalizing the implementation of the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. We note that as described in section III.A.2.c. of the preamble of this final rule, we are finalizing a transition for hospitals that would see a decrease of more than 5 percent in their FY 2021 wage index compared to their FY 2020 wage index.

2. Market-Based MS–DRG Relative Weight Estimation Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights

In section IV.P.2.c. of the preamble of this final rule, we are finalizing the adoption of a market-based methodology for estimating the MS–DRG relative weights beginning in FY 2024, based on the median payer-specific negotiated charge information we are finalizing to collect on the cost report. We are finalizing our data collection proposal with modification to only collect the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations, rather than collecting both the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations and for all third party payers, as proposed. The market-based rate information we are finalizing to collect on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, as described previously, for a hospital's MA organization payers. The payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements finalized in the Hospital Price Transparency final rule (84 FR 65524) that can be cross-walked to an MS–DRG. Hospitals would use the payer-specific negotiated charge data that they would be required to make public, as a result of the Hospital Price Transparency final rule, to then calculate the median payer-specific negotiated charges (as described further in section IV.P.2.c. of this final rule) to report on the Medicare cost report. We are not finalizing the collection of alternative market-based data, such as the median negotiated reimbursement amount, as initially discussed in section IV.P.2.c. of the proposed rule, or any refinements to the definition of median payer-specific negotiated charge.

In section IV.P.2.d. of the preamble of this final rule, we also finalize the adoption of a new market-based methodology for estimating the MS–DRG relative weights, beginning in FY 2024. This market-based methodology is based on the median payer-specific negotiated charge information collected on the Medicare cost report. In the proposed rule we considered alternatives to this approach, such as the use of the median payer-specific negotiated charge for all third-party payers (instead of the median payer-specific negotiated charge for all MA organizations), other alternative collections

of payer-specific negotiated charges, or other market-based information such as a median negotiated reimbursement amount that a hospital negotiates with its MA organizations or third party payers (as described further in section IV.P.2.c of the preamble of the proposed rule), within the MS–DRG relative weight methodology.

We stated in the proposed rule that the same MS–DRG relative weight calculation described in section IV.P.2.d. would be used if we finalized an alternative to the median payer-specific negotiated charge information that we proposed to collect on the Medicare cost report, as further described in that section. We are not finalizing at this time a transition period to this market-based MS–DRG relative weight methodology, but did consider this, and will continue to consider this for future rulemaking prior to the FY 2024 effective date. We remain open to adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date.

P. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This final rule is considered to be an E.O. 13771 regulatory action.

Q. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $3.528 billion in FY 2021, including operating, capital, and new technology changes as modeled for this final rule. The estimated change in operating payments is approximately $3.022 billion (discussed in section I.G. and I.H. of this Appendix). The estimated change in capital payments is approximately $0.027 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately $0.479 billion as discussed in section I.H. of this Appendix. The change in new technology add-on payments reflects the net impact of new, continuing, and expiring current new technology add on payments. Total may differ from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the final MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 0.2 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there would be a $27 million increase in capital payments in FY 2021 compared to FY 2020.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments in FY 2021. In the impact analysis, we are using the final rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2021. Accordingly, based on the best available data for the 363 LTCHs in our database, we estimate that overall FY 2021 LTCH PPS payments will decrease approximately $40 million relative to FY 2020 primarily as a result of the end of the statutory transition period for site neutral payment rate cases.

R. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. In the FY 2021 IPPS/LTCH PPS proposed rule, due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, and consistent with our approach in previous rulemakings (82 FR 38585; 83 FR 41777), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the rule. We welcomed any public comments on the approach in estimating the number of entities that will review this final rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Therefore, for the purposes of our estimate, and consistent with our approach in previous rulemaking (82 FR 38585; 83 FR 41777), we assume that each reviewer read approximately 50 percent of the rule. In the proposed rule, we welcomed public comments on this assumption. We did not receive any public comments specific to our solicitation.

We have used the number of timely pieces of correspondence on the FY 2021 IPPS/LTCH PPS proposed rule as our estimate for the number of reviewers of the final rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 25.94 hours for the staff to review half of this proposed or final rule. For each entity that reviews the rule, the estimated cost is $2,873 (25.94 hours × $110.74). Therefore, we estimate that the total cost of reviewing this regulation is $2,476,579 ($2,873 × 862).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the final changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies adopted in this final rule are estimated at $3.528 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2020 TO FY 2021

Category	Transfers
Annualized Monetized Transfers	$3.528 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the final payment rates and factors presented in this final rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2021 relative to FY 2020 of approximately $40 million based on the data for 363 LTCHs in our database

that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at: *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the final payment rates and factors and other provisions presented in this final rule based on the data for the 363 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at −$40 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2020 LTCH PPS TO THE FY 2021 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$40 million
From Whom to Whom	LTCH Medicare Providers to Federal Government

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this final rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. For example, we refer readers to ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2021.'' Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities because they do not meet the SBA definition of a small business. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this final rule constitutes our regulatory flexibility analysis. This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

For purposes of the RFA, as stated previously, all hospitals and other providers and suppliers are considered to be small entities. We estimate the provisions of this final rule would result in an estimated $3.528 billion increase in FY 2021 payments to IPPS hospitals, primarily driven by the applicable percentage increase to the IPPS rates in conjunction with other payment changes including uncompensated care payments, capital payments, and new technology add-on payments, as discussed in section I.B. of this Appendix. As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2021 relative to FY 2020 of approximately $40 million. We solicited public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses are presented throughout this final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds and 50–99 beds are expected to experience an increase in payments from FY 2020 to FY 2021 of 2.0 percent and 2.1 percent, respectively. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the final policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act (UMRA) Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold level is approximately $156 million. This final rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this final rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act.

As discussed in section IV.G.4 of the preamble of this final rule, CMS sought comment in the proposed rule on a potential restructuring of the Medicare DSH and uncompensated care payments specific to IHS and Tribal hospitals beginning in FY 2022. Consistent with Executive Order 13175, we continue to engage in consultation with Tribal officials on this issue. We intend to use input received from these consultations with Tribal officials, as well as the comments on the proposed rule, to inform future rulemaking.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this final rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2021, consistent with our approach for FY 2020, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2021

A. FY 2021 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this final rule, for FY 2021, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets effective beginning in FY 2018.

In the FY 2021 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed to base the proposed FY 2021 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2019, which was estimated to be 3.0 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of the FY 2021 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2019 forecast, we proposed a MFP adjustment of 0.4 percentage point for FY 2021. We also proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2021 market basket update and MFP adjustment for the final rule.

In the FY 2021 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket and the MFP adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented four possible applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are establishing the applicable percentages increase for the FY 2021 updates based on IGI's second quarter 2020 forecast of the 2014-based IPPS market basket of 2.4 percent and the MFP adjustment of 0.0 percentage point, as discussed in section IV.B., depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as shown in the table in this section.

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.6	-0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.8	0	-1.8
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	0	0	0	0
Applicable Percentage Increase Applied to Standardized Amount	**2.4**	**0.6**	**1.8**	**0.0**

B. Update for SCHs and MDHs for FY 2021

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2021 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2021 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56939), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this final rule. Accordingly, for FY 2021, we are establishing an applicable percentage increase of 2.4 percent to the standardized amount for hospitals located in Puerto Rico.

D. Update for Hospitals Excluded From the IPPS for FY 2021

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this final rule, in the FY 2018 IPPS/LTCH PPS final rule, we finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. In addition, as discussed in section IV.B. of the preamble of this final rule, the update to the target amount for extended neoplastic disease care hospitals for FY 2021 is the percentage increase in the 2014-based IPPS operating market basket. Accordingly, for FY 2021, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2021 percentage increase in the 2014-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2021 is 2.4 percent.

E. Update for LTCHs for FY 2021

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are establishing an update to the LTCH PPS standard Federal payment rate for FY 2021 of 2.3 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment of 0.0 percentage point described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the MFP adjustment). Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.023 in determining the LTCH PPS standard Federal rate for FY 2021. For LTCHs that fail to submit quality data for FY 2021, we are establishing an annual update to the LTCH PPS standard Federal rate of 0.3 percent (that is, the annual update for FY 2021 of 2.3 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a update factor of 1.003 in determining the LTCH PPS standard Federal rate for FY 2021. (We note that, as discussed in section VII.D. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 2.3 percent for FY 2021 does not reflect any budget neutrality factors).

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update of 2.0 percent. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 2.4 percent.

For FY 2021, consistent with policy set forth in section VII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 2.3 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2021, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.3 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2020 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by 2 percent with the difference between this and the update amount specified in current law to be used to increase payments under MedPAC's Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' MedPAC stated that together, these recommendations, paired with the recommendation to eliminate the current hospital quality program incentives, would increase hospital payments by increasing the base payment rate and by increasing the average rewards hospitals receive under MedPAC's Medicare HVIP. We refer readers to the March 2020 MedPAC report, which is available for download at *www.medpac.gov,* for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 2 percent, with the remainder of the applicable percentage increase specified in current law to be used to fund its recommended Medicare HVIP, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2021 applicable percentage increase. Therefore, consistent with the statute, we are establishing an applicable percentage increase for FY 2021 of 2.4 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. Furthermore, we appreciate MedPAC's recommendation concerning a new HVIP. We agree that continual improvement motivated by quality programs is an important incentive of the IPPS.

We note that, because the operating and capital payments in the IPPS remain

separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

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