Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4159–F2]

RIN 0938–AS20

Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

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

ACTION: Final rule.

SUMMARY: This final rule amends the Medicare Advantage (MA) program (Part C) regulations and Medicare Prescription Drug Benefit Program (Part D) regulations to implement statutory requirements; improve program efficiencies; strengthen beneficiary protections; clarify program requirements; improve payment accuracy; and make various technical changes. Additionally, this rule finalizes two technical changes that reinstate previously approved but erroneously removed regulation text sections.

DATES: This rule is effective March 16, 2015, except amendments to § 423.154, which are effective January 1, 2016.

Applicability Dates: Except as specified in Table 1, the applicability date of these provisions is January 1, 2016. In the Supplemental section of this final rule, we provide a table (Table 1) that lists changes in this final rule that have either an effective date other than March 16, 2015 or an applicability date other than January 1, 2016, for Contract Year 2016.

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SUPPLEMENTARY INFORMATION: The majority of the provisions listed in this rule are intended for implementation for contract year 2016. Changes in the Code of Federal Regulations (CFR) will be consistent with the effective date of the applicable provision. Table 1 lists those provisions with effective dates other than 30 days after the date of publication of this final rule or applicability dates other than January 1, 2016 for contract year 2016. The applicability and effective dates are discussed in the preamble for each of these items.

TABLE 1—APPLICABILITY AND EFFECTIVE DATES OF SELECT PROVISIONS OF THE FINAL RULE

Preamble section	Section title	Effective date	Applicability date
II.A.2.	Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§§ 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, and 423.44).	.....	June 1, 2015.
II.A.5.	Efficient Dispensing in Long-Term Care Facilities and Other Changes (§ 423.154)	January 1, 2016.	

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Acronyms

ADS Automatic Dispensing System
AHFS American Hospital Formulary Service
AHFS–DI American Hospital Formulary Service-Drug Information
AHRQ Agency for Health Care Research and Quality
ANOC Annual Notice of Change
AO Accrediting Organization
ALR Assisted Living Residence
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106–554)
BLA Biologics License Application
BLS Bureau of Labor Statistics
CAHPS Consumer Assessment Health Providers Survey
CAP Corrective Action Plan
CCIP Chronic Care Improvement Program
CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
CCS Certified Coding Specialist
CDC Centers for Disease Control
CGDP Coverage Gap Discount Program
CHIP Children's Health Insurance Programs
CMP Civil Money Penalty
CMR Comprehensive Medical Review
CMS Centers for Medicare & Medicaid Services
CMS–HCC CMS Hierarchal Condition Category
CTM Complaints Tracking Module
COB Coordination of Benefits
CORF Comprehensive Outpatient Rehabilitation Facility
CPC Certified Professional Coder
CY Calendar Year
DEA Drug Enforcement Administration
DIR Direct and Indirect Remuneration
DHS Department of Homeland Security
DME Durable Medical Equipment
DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
D-SNPs Dual Eligible SNPs
DOL U.S. Department of Labor
DUR Drug Utilization Review
EAJR Expedited Access to Judicial Review
EGWP Employer Group/Union-Sponsored Waiver Plan
EOB Explanation of Benefits
EOC Evidence of Coverage
ESRD End-Stage Renal Disease
FACA Federal Advisory Committee Act
FDA Food and Drug Administration
FDR First-tier, Downstream, and Related Entities
FEHBP Federal Employees Health Benefits Plan
FFS Fee-For-Service
FIDE Fully-integrated Dual Eligible
FIDE SNPs Fully-integrated Dual Eligible Special Needs Plans
FMV Fair Market Value
FY Fiscal Year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
HCPP Health Care Prepayment Plans
HEDIS HealthCare Effectiveness Data and Information Set
HHS [U.S. Department of] Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191)
HMO Health Maintenance Organization
HOS Health Outcome Survey
HPMS Health Plan Management System
ICFs/IID Intermediate care facilities for the mentally retarded
ICL Initial Coverage Limit
ICR Information Collection Requirement
ID Identification
IMD Institutes for mental disease
IT Information Technology
I/T/U Pharmacies Indian Health Service, Tribes and Tribal organizations, and urban Indian organizations (collectively referred to as ''I/T/U'').
IVC Initial Validation Contractor
LCD Local Coverage Determination
LEP Late Enrollment Penalty
LIS Low-Income Subsidy
LPPO Local Preferred Provider Organization
LTC Long Term Care
MA Medicare Advantage
MAAA Member of the American Academy of Actuaries
MA–PD Medicare Advantage-Prescription Drug Plan
MCO Managed Care Organization
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MOC Medicare Options Compare
MOOP Maximum Out-of-Pocket
MPDPF Medicare Prescription Drug Plan Finder
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MS–DRG Medicare Severity Diagnosis Related Group
MSA Metropolitan Statistical Area
MSAs Medical Savings Accounts
MSP Medicare Secondary Payer
MTM Medication Therapy Management
MTMP Medication Therapy Management Program
NAIC National Association of Insurance Commissioners
NCPDP National Council for Prescription Drug Programs
NCQA National Committee for Quality Assurance
NDA New Drug Application
NDC National Drug Code
NGC National Guideline Clearinghouse
NIH National Institutes of Health
NOMNC Notice of Medicare Non-Coverage
NPI National Provider Identifier
OES Occupational Employment Statistics
OIG Office of Inspector General
OMB Office of Management and Budget
OPM Office of Personnel Management
OTC Over the Counter
PACE Programs of the All-Inclusive Care for the Elderly
Part C Medicare Advantage
Part D Medicare Prescription Drug Benefit Program
Part D IRMAA Part D Income Related Monthly Adjustment Amount
PBM Pharmacy Benefit Manager
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee For Service Plan
POA Present on Admission (Indicator)
POS Point-of-Sale
PPO Preferred Provider Organization
PPS Prospective Payment System
P&T Pharmacy & Therapeutics
QRS Quality Review Study
PACE Programs of All Inclusive Care for the Elderly
PRWORA Personal Responsibility and Work Opportunity Reconciliation Act of 1996
RADV Risk Adjustment Data Validation
RAC Recovery Audit Contractor
RAPS Risk Adjustment Payment System
RPPO Regional Preferred Provider Organization
RTO Return to Operations/Recovery Time Objective
SBA Small Business Association
SCORM Sharable Content Object Reference Model
SEP Special Enrollment Period
SHIP State Health Insurance Assistance Programs
SNF Skilled Nursing Facility
SNP Special Needs Plan
SNP MOC Special Needs Plan Model of Care
SPAP State Pharmaceutical Assistance Programs
SSA Social Security Administration
SSI Supplemental Security Income
T&C Terms and Conditions
TPA Third Party Administrator
TrOOP True Out-Of-Pocket
U&C Usual and Customary
UPIN Uniform Provider Identification Number

USP U.S. Pharmacopoeia
ZPIC Zone Program Integrity Contractor

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The purpose of this final rule is to revise the Medicare Advantage (MA) program (Part C) regulations and Medicare Prescription Drug Benefit Program (Part D) regulations to implement statutory requirements, improve program efficiencies, strengthen beneficiary protections, clarify program requirements, improve payment accuracy, and make various technical changes for contract year 2016.

2. Summary of the Major Provisions

a. Changes to Audit and Inspection Authority (§§ 422.503(d)(2), 423.504(d)(2))

We proposed three changes to our audit and inspection authority. Due to significant concerns raised during the public comment period, we are finalizing only two of those three proposals. First, under section 6408 of the Affordable Care Act, new authority was provided to the Secretary that now requires that each contract provide the right to ''timely'' inspection and audit.

We are revising both §§ 422.503(d)(2) and 423.504(d)(2) to insert the word ''timely'' at the end of both of the introductory paragraphs.

We are also adding language to §§ 422.503(d)(2) and 423.504(d)(2) that will allow us to require that a sponsoring organization hire an independent auditor, working in accordance with CMS specifications, to validate if the deficiencies that were found during a CMS full or partial program audit have been corrected and provide CMS with a copy of the audit findings.

The proposal to require MA organizations and Part D plan sponsors to hire an independent auditor to conduct full or partial program audits will not be finalized.

b. Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§§ 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, 423.44)

After consideration of the public comments, we are finalizing the policies mostly as proposed, with the exception of changes to the regulation text at §§ 417.422, 417.460, 422.50, 423.1, 423.3 and 423.44 to clarify that any individual not lawfully present is no longer eligible to remain enrolled in a cost, MA, or Part D plan, to establish the disenrollment effective date to be the first of the month following notice by CMS of ineligibility, and to delete the term ''qualified alien.'' Further, we are redesignating the current text at § 417.460(b)(2)(iv) as paragraph (b)(2)(v) and finalizing the provision establishing a lack of lawful presence as a basis for disenrollment from a cost plan at paragraph (b)(2)(iv). This provision is consistent with the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) and with recommendations made by the Office of the Inspector General (OIG) in its January 2013 and October 2013 reports.

c. Business Continuity for MA Organizations & PDP Sponsors (§§ 422.504(o) and 423.505(p))

To respond to concerns raised during the comment period, we revised the regulation text by providing a 72, rather than 24 hour, restoration time period for MA organizations and Part D sponsors after a systems failure. We also revised text as necessary to make clear that we require MA organizations and sponsors to ''plan to'' restore essential functions within the 72-hour time period, rather than guarantee complete restoration within the timeframe. Some commenters thought our intent was to require continuous operations under all conditions, and we revised language from the proposed regulation to make clear that that was not the case in our final rule. Lastly commenters distinguished between Part C and D operations and noted, for instance, that provider payments are not a 24-hour critical function for MA plans since payment is allowed to be made within 30 days and that health and safety would not be put at risk by failure of Part C claims processing and appeals processing. We removed language related to that requirement for MA plans.

d. Efficient Dispensing in Long Term Care Facilities and Other Changes (§ 423.154)

We are finalizing changes to the rule requiring efficient dispensing to Medicare Part D enrollees in long term care (LTC) facilities. Some Part D sponsors (or their pharmacy benefit managers) implemented the short-cycle dispensing requirement by pro-rating monthly dispensing fees, which penalize the offering and adoption of more efficient LTC dispensing techniques compared to less efficient LTC dispensing techniques. This is because when a medication is discontinued before a month's supply has been dispensed, a pharmacy that dispenses the maximum amount of the medication at a time permitted under § 423.154 (which is 14 days' supplies), collects more in dispensing fees than a pharmacy that utilizes dispensing techniques that result in less than maximum quantities being dispensed at a time. In other words, a less efficient pharmacy collects more in dispensing fees than a more efficient pharmacy. This is contrary to the Congress' intent in enacting section 3310 of the Affordable Care Act, which is to reduce medication waste. Therefore, we have finalized a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. We have also finalized a requirement to ensure that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques. Other changes to the rule requiring efficient dispensing to Medicare Part D enrollees in LTC facilities are eliminating language that has been misinterpreted as requiring the proration of dispensing fees and making a technical change to the requirement that Part D sponsors report on the nature and quantity of unused brand and generic drugs. We are not finalizing an additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions at this time.

3. Summary of Costs and Benefits

TABLE 2—SUMMARY OF COSTS AND BENEFITS

Provision	Total costs	Transfers
Changes to Audit and Inspection	We estimate that this change would require an annual cost of $2 million for the time and effort for all MA organizations or Part D sponsors with audit results that reveal non-compliance with CMS requirements to hire independent auditors to validate that correction has occurred. The total cost for 2015–2019 is estimated to be $10 million.	
Eligibility of enrollment for individuals not lawfully present in the U.S.	N/A	We estimate that this change could save the MA program up to $5 million in 2015, increasing to $8 million in 2019 (total of $32 million over this period), and could save the Part D program (includes the Part D portion of MA–PD plans) up to $5 million in 2015, increasing to $9 million in 2019 (total of $35 million over this period).
Business Continuity Operations	We estimate that this change would require a first year cost of $8 million in 2015, for the time and effort for affected organizations to comply with the business continuity requirements. In subsequent years, 2016–2019, the cost for maintaining the business continuity is estimated to be $4 million. The total cost over the period 2015–2019 is estimated to be $24 million.	

B. Background

1. General Overview and Regulatory History

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the MA program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) entitled the Medicare Prescription Drug Benefit Program (Part D), and made significant changes to the existing Part C program, which it named the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, in the September 18, 2008 and January 12, 2009 **Federal Register** (73 FR 54226 and 74 FR 1494, respectively), we issued Part C and D regulations to implement provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule on January 16, 2009 (74 FR 2881) to address MIPPA provisions related to Part D plan formularies. In the final rule that appeared in the April 15, 2010 **Federal Register** (75 FR 19678), we made changes to the Part C and D regulations which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 **Federal Register** (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act (Pub. L. 111–152) (collectively the Affordable Care Act or ACA) added a number of new Medicare provisions and modified many existing provisions. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

In a final rule that appeared in the April 12, 2012 **Federal Register** (77 FR 22072 through 22175), we made several changes to the Part C and Part D

programs required by statute, including the Affordable Care Act, and made improvements to both programs through modifications reflecting experience we have obtained administering the Part C and Part D programs. Key provisions of that final rule implemented changes closing the Part D coverage gap, or ''donut hole,'' for Medicare beneficiaries who do not already receive low-income subsidies from us by establishing the Medicare Coverage Gap Discount Program. We also included provisions providing new benefit flexibility for fully-integrated dual eligible special needs plans, clarifying coverage of durable medical equipment, and combatting possible fraudulent activity by requiring Part D sponsors to include an active and valid prescriber National Provider Identifier on prescription drug event records.

2. Issuance of the Proposed Rule

In the proposed rule titled ''Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' which appeared in the January 10, 2014 **Federal Register** (79 FR 1918), we proposed to revise the MA program (Part C) regulations and Medicare Prescription Drug Benefit Program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; improve program efficiencies; and clarify program requirements. The proposed rule also included several provisions designed to improve payment accuracy.

3. Public Comments Received in Response to the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule

We received approximately 7,600 timely pieces of correspondence containing multiple comments on the CY 2015 proposed rule. The majority of correspondence received was in reference to provisions that were either finalized in the final rule that appeared in the **Federal Register** on May 23, 2014 (79 FR 29844) (May 2014 final rule) or that will not be finalized. While we are finalizing in whole or in part approximately 30 of the provisions from the proposed rule in this final rule, there remain a small number of provisions from the proposed rule that were not finalized in the May 2014 final rule and that we are not finalizing in this rule. These provisions are listed later in this section in Table 2.

Public comments on the provisions finalized in this rule were submitted between January 10, 2014 and March 7, 2014. We note that some of the public comments were outside of the scope of the proposed rule provisions that we are finalizing here. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing comments received with respect to the provisions of the proposed rule that we are not finalizing.

TABLE 2—PROVISIONS NOT BEING FINALIZED

Proposed Rule January 10, 2014 **Federal Register** (79 FR 1918), section	Topic
	Clarifying Various Program Participation Requirements
III.A.2	Two-year Limitation on Submitting a New Bid in an Area Where an MA has been Required to Terminate a Low-enrollment MA Plan (§ 422.504(a)(19)).
III.A.9	Collections of Premiums and Cost Sharing (§ 423.294).
III.A.12	Separating the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC) (§ 422.111(a)(3) and 423.128(a)(3)).
III.A.14	Exceptions to Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(vi)).
III.A.15	Medication Therapy Management Program (MTMP) under Part D (§ 423.153(d)(1)(v)(A))—outreach strategies.
III.A.23	Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325)—disclosure requirement for Part D sponsors.
III.A.26	Payments to PDP Plan Sponsors For Qualified Prescription Drug Coverage (§ 423.308) and Payments to Sponsors of Retiree Prescription Drug Plans (§ 423.882).
III.A.38	Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D-SNPs) to another D-SNP to Support Alignment Procedures (§ 422.60).
	Strengthening Beneficiary Protections
III.C.1	Providing High Quality Health Care (§ 422.504(a)(3) and § 423.505(b)(27)).
III.C.4	Definition of Organization Determination (§ 422.566).
	Strengthening our Ability To Distinguish Stronger Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers
III.D.4	Termination of the Contracts of Medicare Advantage Organizations Offering PDP for Failure for 3 Consecutive Years to Achieve 3 Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year (§ 422.510).
	Implementing Other Technical Changes
III.E.2	Skilled Nursing Facility Stays (§§ 422.101 and 422.102).

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Clarifying Various Program Participation Requirements

1. Changes to Audit and Inspection Authority (§§ 422.503(d)(2), 423.504(d)(2))

Sections 1857(d)(2)(A) and 1860D–12(b)(3)(C) of the Act specify that each contract under these sections must state that CMS has the right to audit and inspect the facilities and records of each organization. We proposed three changes to our audit and inspection authority. First, under section 6408 of the Affordable Care Act, new authority was provided to the Secretary that now requires that each contract provide the right to ''timely'' inspection and audit.

We proposed to revise both §§ 422.503(d)(2) and 423.504(d)(2) to reflect this change. Specifically, we proposed to insert the word ''timely'' at the end of both of the introductory paragraphs for §§ 422.503(d)(2) and 423.504(d)(2).

We also proposed to add language to §§ 422.503(d)(2) and 423.504(d)(2) that will allow us to require an MA organization or Part D plan sponsor to hire an independent auditor, working in accordance with CMS specifications, to perform full or partial program audits to determine compliance with CMS requirements and provide to CMS an attestation affirming that the audit has been completed as required.

Lastly, we proposed to add language to §§ 422.503(d)(2) and 423.504(d)(2) that would allow us to require that a sponsoring organization hire an independent auditor, working in accordance with CMS specifications, to validate if the deficiencies that were found during a CMS full or partial program audit have been corrected and provide CMS with a copy of the audit findings.

We received the following comments and our responses follow:

Comment: Some commenters requested that CMS define ''timely'' as it is being added to § 422.503(d)(2) and § 423.504(d)(2) and that CMS define the existing language from paragraph (2) in that same section, specifically: ''when there is reasonable evidence for some need for such inspection.''

Response: We are following the exact working of the statute in adding the word ''timely'' to our current audit and inspection authority. We believe that the Congress recognized that what would be considered ''timely'' is based on a reasonableness standard that may change based on the specific circumstances leading up to the audit. For example, we currently give sponsors 4-weeks notice prior to the start of a routine program audit and we do not envision this change altering that practice. However, if we were to become aware of a situation where beneficiaries' health or safety may be at risk based on a plan's poor performance, we will reserve the right to request records or any needed documentation in an expedited fashion. Therefore, we will not put restrictions on the broadly stated statutory language and believe that this is in line with the spirit and intent of the statutory change. Similarly, the language in paragraph (2) in that same section is not a change, but existing language from our regulations. Again, we believe that the wording is appropriate and does not require additional definition or explanation.

Comment: One commenter suggested we utilize the NCPDP audit standard as a means of standardizing audit communications.

Response: We appreciate the commenter's suggestion and believe this would be a more appropriate approach if our audits largely focused on claim level audits between MA and Part D organizations and the providers or entities they pay. However, program audits cover a wide range of our program areas and corresponding programmatic requirements, many of which go well beyond claim determinations. We have received positive feedback from MA and Part D organizations in the past regarding the level of detail and useful information and feedback in our audit reports, which sponsors rely upon as they work towards implementing any necessary corrective actions. By limiting the communication to the codes and auditing standards used by NCPDP, we believe that—(1) many of our findings would not be adequately covered by these standards; and (2) they would not provide enough detail in many cases to allow for an organization to undertake meaningful correction.

Comment: A commenter suggested that CMS specify that the same organization that performed the audit also perform the validation in order to ensure consistency in interpretation and try to keep costs down, or at the very least require at least one member from the original audit team be a member of the validation team.

Response: We will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing the proposal that we may require an organization to hire an independent auditor to validate correction of audit deficiencies. We will consider the recommendation to include a member from the original audit team in any validation activities whether they be performed by CMS internally or by an independent auditor hired by the MA or Part D organization at CMS' request.

Comment: Some commenters' requested if CMS would set a time limit in which audits must be completed or conducted.

Response: We will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing our proposal that we may require an organization to hire an independent auditor to validate correction of audit deficiencies. We will establish a timeframe in subregulatory guidance based on our current internal validation audit timeline. However, we recognize that some correction activities require more time than others, we will reserve the right to alter those timelines for deficiencies that we believe—(1) a more immediate correction is warranted due to the potential for beneficiary harm; or (2) require a longer correction timeline due to the technical or difficult nature of correction (for example, rebuilding or completely restructuring systems infrastructure).

Comment: A commenter requested if CMS would pay for the cost to hire an independent auditor.

Response: Our proposal was that an MA or Part D organization would retain the independent auditing firm to conduct the audit, but that the plan could account for the costs in their bid. However, we will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing our proposal that we may require an organization to hire an independent auditor to validate correction of audit deficiencies.

Comment: Some commenters requested that CMS cap fees that independent audit firms would charge MA and Part D organizations to perform program audits.

Response: If we decide to pursue this proposal in the future, we will explore our ability to cap the costs of performing these audit activities.

Comment: Many commenters suggested that instead of requiring MA and Part D organizations to hire independent auditors to expand the number of audits conducted each year that we look to the various other compliance and monitoring activities the Agency engages in, which could be used to better target audits or results could be utilized in lieu of audit activities.

Response: We do utilize the data and information obtained about sponsor performance to target our audit efforts as part of the overall risk assessment used to select sponsors for audit. We have also utilized data and information from our various monitoring efforts to assist in determining if certain deficiencies discovered during an audit may have been corrected (for example, if a sponsor had multiple deficiencies in a program area that will at a later date be the subject of a monitoring activity, we may use passing results from that monitoring activity as proof of correction).

Comment: A commenter requested that CMS release the data driven elements of the risk assessment and define a sponsor who is high risk.

Response: We believe that this comment is outside the scope of this final rule. However, we use a variety of existing data points from Medicare Star ratings, past performance and plan reported data, as a few examples, to develop our risk assessment. We focus on metrics that have the potential to affect beneficiary access to medications and services, and also look for operational metrics that program experience has demonstrated can cause contracting organizations to develop performance problems in core program areas (that is, large increases in enrollment over a short period of time). We do not release our risk assessment in its entirety, but these are the areas we focus on when conducting the analysis. Organizations should note that it is our goal to audit all organizations in the MA and Part D program, and the risk assessment is one way plans are selected for audit.

Comment: Some commenters raised concerns over their available recourse if they disagreed with an independent auditor's findings, given the impact on Medicare Star ratings and past performance.

Response: We will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing the proposal that we may require an organization to hire an independent auditor to validate correction of audit deficiencies. Validation results have no impact on Medicare Star ratings or past performance. However, we stated in the proposal that organizations would have an opportunity to rebut audit findings, this would include during validation efforts, and CMS would be reviewing both draft and final reports from the independent auditor. Therefore, we would give organizations an avenue to dispute findings or policy interpretations that organizations believed to be erroneous, even in the more limited use of an independent auditor to validate correction of deficiencies.

Comment: A commenter stated that our proposal did not clarify how organizations hiring an independent auditor to conduct full or partial program audits would affect or involve the Zone Program Integrity Contractors (ZPICs) or the Recovery Audit Contractors (RACs).

Response: The proposal to utilize an independent auditor to conduct full or partial program audits or validations has no impact on ZPICs or RACs, which is why they are not mentioned in our proposal.

Comment: Several commenters suggested that CMS develop a core set of SNP auditors regardless of whether or not we implement our independent auditor proposal, given what the industry perceives as inexperienced or inconsistent SNP findings amongst auditors, which many SNPs believed would be aggravated if organizations were required to retain an independent audit firm. Some suggested that SNP auditors should be accredited by NCQA prior to being allowed to conduct SNP audits.

Response: We believe that this is outside the scope of this proposal, but we thank the commenter for their suggestion to continue to strengthen the CMS MA and Part D audit program. We have conducted additional training and continue to welcome feedback on all of our audit processes and protocols. After the piloting of the SNP MOC protocols in 2013, we conducted specialized feedback sessions with organizations subject to SNP MOC audits and made changes to our protocols, methods of evaluation and training of auditors based on the industry's feedback. We welcome additional feedback and hope that organizations will see continual improvements in our audit processes in 2014 and future years.

Comment: A commenter inquired if the independent auditor proposals applied to PACE organizations.

Response: No, these proposals do not apply to PACE organizations. These regulatory provisions do not apply to PACE plans because we are only proposing changes to Parts 422 and 423 which govern MA, other Managed care plans, and Part D organizations. PACE plans are governed by the regulations in part 460. With respect to this change applying to cost plans, we select sponsors for audit at their parent organization level, and if they have an 1876 cost plan, that contract would be included in our audit. Therefore, the parent organization may be requested to hire an independent auditor to validate the correction of their audit deficiencies. However, if an organization was a standalone cost plan, with no MA or Part D contracts under parts 422 or 423, this requirement would not apply to those organizations, as cost plans are governed by part 417.

Comment: A commenter suggested that CMS develop and implement a robust annual or biannual training program for independent auditors to ensure that they were competent to perform program audits properly.

Response: We will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing the proposal that CMS may require an organization to hire an independent auditor to validate correction of audit deficiencies. We will consider this suggestion if we repropose the larger full scale use of independent auditors to conduct full or partial program audits in the future. We will also share whatever materials we have developed and can provide technical assistance if we request an organization to retain an independent auditor to validate correction of audit deficiencies.

Comment: A commenter suggested that instead of requiring plans to hire an independent auditor we require plans to conduct a robust internal audit and share the results with CMS.

Response: We will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing the proposal that CMS may require an organization to hire an independent auditor to validate correction of audit deficiencies. We currently require organizations to conduct internal auditing and monitoring as part of having an effective compliance program, which we believe for purposes of a healthy and robust compliance program, such activities are appropriate.

Comment: A commenter recommended that much like CMS' use of independent auditors to conduct data validation audits, CMS should set criteria regarding who can conduct program audits. For example, the commenter suggested CMS clarify that organizations that currently assist plans with operations, compliance or consulting are disqualified from performing as independent auditors.

Response: We will not be finalizing the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing the proposal that CMS may require an organization to hire an independent auditor to validate

correction of audit deficiencies. We thank the commenter for their suggestion with respect to whom a contracting organization may retain to perform validation of correction of audit deficiencies. We will consider including any key criteria regarding who can perform these validations in subsequent subregulatory guidance.

Comment: A few commenters questioned whether CMS has the statutory authority to require contracting organizations to retain an independent auditor to conduct full or partial program audits. These commenters raised many related issues, such as CMS trying to inappropriately expand their appropriation by requiring contracting organizations to bear the cost of hiring an audit firm to perform a function that the Congress has tasked CMS with performing. Other commenters stated that to the extent these funds expended by plans were later reimbursed by CMS through the bid process, it could implicate the Anti-Deficiency Act.

Response: We will not finalize the proposal requiring organizations to hire an independent auditor to conduct full or partial program audits, but we are finalizing the proposal that we may require an organization to hire an independent auditor to validate correction of audit deficiencies. We do not agree that our proposal allowing us the option to request a plan sponsor to retain an independent auditor to verify that deficiencies that we determined existed during our audit have been corrected implicates the concerns that organizations previously raised regarding our current appropriation or statutory authority. The proposal simply mirrors our current authority where we may require organizations under sanction to retain an independent auditor to perform an independent review to validate that the deficiencies upon which the sanction was based have been corrected and are not likely to recur.

After consideration of all of the comments received, we are finalizing our proposal to revise both §§ 422.503(d)(2) and 423.504(d)(2) to insert the word ''timely'' at the end of both of the introductory paragraphs for §§ 422.503(d)(2) and 423.504(d)(2), and our proposal to have the option to require contracting organizations who were found to have deficiencies during a CMS program audit to hire an independent auditor to validate correction of those deficiencies.

However, based on the strong opposition and valid concerns raised by contracting organizations, we have decided at this time not to finalize our proposal to require plan sponsors to hire an independent auditor no less than every 3 years to conduct full or partial program audits.

2. Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§§ 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, and 423.44)

a. Basic Enrollment Requirements

Sections 226 and 226A of the Act establish the conditions for Medicare Part A entitlement for individuals who have attained age 65, are disabled or have end stage renal disease (ESRD), and are entitled to monthly Social Security benefits under section 202 of the Act; individuals entitled to Part A under these sections do not have to pay premiums for such coverage, and they may, but are not required to, enroll in Medicare Part B. Section 1818 of the Act establishes the conditions for Medicare enrollment for individuals who are not entitled to Medicare Part A without a premium under sections 226 or 226A of the Act. Individuals must have Part B (under section 1836 of the Act) and must also meet citizenship or alien status requirements in order to purchase Part A hospital insurance under section 1818 of the Act; individuals covered under section 1836 of the Act must meet citizenship or alien status requirements, in addition to other requirements, in order to enroll in Part B if they are not entitled to premium-free Medicare under sections 226 or 226A.

Sections 1851(a)(3)(B), 1860D 1(a)(3)(A), and 1876(a)(1)(A) of the Act outline the eligibility requirements to enroll in MA (Part C), Medicare prescription drug coverage (Part D), and Medicare cost plans. To be eligible for MA, Part D, or cost plan coverage, individuals must have active Medicare coverage. Specifically, to enroll in MA, an individual must be entitled to benefits under Part A and be enrolled in Part B; to enroll in Part D, an individual must be entitled to Part A and/or enrolled in Part B; to enroll in a Medicare cost plan, an individual must be enrolled in Part B (Part A entitlement is not required).

b. Medicare Eligibility and Lawful Presence

Section 401 of the PRWORA, amended by section 5561 of the Balanced Budget Act, limits the eligibility of individuals who are not qualified aliens to receive benefits under certain federal programs, including benefits under Title XVIII of the Act (Medicare); these provisions are codified at 8 U.S.C. 1611 and 1641. In general pursuant to 8 U.S.C. 1611(a), an alien who is not a qualified alien is not eligible to receive any federal public benefit. The Congress has established some exceptions to this general rule. One exception, at 8 U.S.C. 1611(b)(3), permits certain aliens to obtain Medicare benefits and applies to an alien who is: (1) Lawfully present in the United States, as determined by the Attorney General and (2) was authorized to be employed with respect to wages attributable to employment, which were counted for the purpose of determining Medicare entitlement under Part A [1]. An alien who is eligible under this exception is able to receive any benefit payable under Medicare. In contrast, an alien that is not lawfully present in the United States is not eligible to receive benefits under Medicare.

As a result, individuals meeting certain criteria are able to earn qualified credits towards Social Security retirement benefits as outlined in 8 U.S.C. 1631 (federal attribution of sponsor's income and resources to alien) and 8 U.S.C. 1645 (Qualifying quarters). Such individuals may earn the total number of qualified credits to be eligible under the Act to receive retirement benefits under sections 226 and 226A of the Act. However, should such individuals be unlawfully present in the United States, under PRWORA they are not eligible to receive the Social Security benefits they have earned for as long as they remain unlawfully present. When they are again lawfully present in the United States, or live outside the United States, they would regain eligibility to receive Social Security payments.

Similarly, when those not lawfully present become eligible for Medicare based on age or disability under the Act, they would also automatically be entitled under the Act to premium free Part A benefits and be eligible under the Act to enroll in Part B during a valid enrollment period. Furthermore, if these same individuals were receiving Social Security retirement benefits 4 months prior to turning 65, or are in their 21st month of receiving Social Security disability benefits, they would also automatically be enrolled into both Part A and Part B, consistent with section 1837 of the Act and the enrollment process outlined in § 407.17. However, again under the PRWORA limitations previously discussed, payments for Medicare benefits cannot be made on behalf of these individuals as long as they are not lawfully present in the United States. Only upon becoming lawfully present would they become

[1] This includes qualified aliens.

eligible to receive the Medicare benefits to which they would otherwise be entitled by paying into Social Security for the requisite number of quarters or paying premiums.

We note that current regulations at §§ 406.28 and 407.27 outline the reasons for loss of premium Part A and Part B enrollment, and do not include the absence of lawful presence or citizenship as a reason for loss of entitlement. Similarly, individuals who are entitled to Part A and enrolled in Part B based on eligibility for Social Security benefits currently may be enrolled in Medicare even if they are not lawfully present in the United States. However, as previously outlined, Medicare benefits are not payable for individuals who are not lawfully present even if such individuals are enrolled in Medicare. Thus, there is a distinction between being ''entitled to Part A'' or ''enrolled in Part B'' as provided for in the Act and being eligible to receive the Part A and Part B benefits that ordinarily flow from such entitlement and enrollment.

c. Alignment of MA, Part D, and Cost Plan Eligibility With Fee for Service (FFS) Payment Exclusion Policy

In order to implement 8 U.S.C. 1611 and ensure that benefits are not incorrectly paid for individuals who are present in the United States unlawfully, the Social Security Administration (SSA) established internal policies and procedures to suspend Social Security benefits during periods in which individuals are not lawfully present in the United States. Because Medicare entitlement flows from entitlement to Social Security retirement and disability benefits, Medicare has also implemented this provision through its own payment exclusion process.

Under Medicare's payment exclusion process, data on lawful presence are transmitted to CMS from the Department of Homeland Security (DHS) via regular data exchanges with SSA. Once the data are received by CMS, lawful presence status is noted on an individual's record and is retained in the FFS claims processing systems. As a result, payment of Part A and Part B claims for non-citizens is denied where lawful presence is not established on their record, and continues to be denied until these individuals regain lawful presence status. Although payment is being denied for claims, individuals who are entitled to Medicare per section 226 of the Act, maintain Part A entitlement and remain enrolled in Part B on Medicare's records as long as Part B premiums are paid. Similarly, individuals who are enrolled in premium Part A or Part B or both under sections 1818 and 1836 of the Act, maintain their enrollment status as long as premiums are paid.

We proposed to align eligibility for enrollment in MA, Part D, and cost plans (and resulting Medicare payments to plans and by plans that would violate PRWORA) with the FFS payment exclusion policy to ensure that Medicare is only paying for benefits and services rendered to individuals who are eligible to receive them. These steps align with the recommendations made by the Office of Inspector General (OIG) in its January 2013 report (A–07–12–01116) [2] regarding the need for CMS to maintain adequate controls to detect and prevent improper payments for Medicare services rendered to beneficiaries who are not lawfully present. Accordingly, we proposed to revise the regulations to establish U.S. citizenship and lawful presence as eligibility requirements for enrollment in MA, Part D, and cost plans. Further, we proposed that individuals who are not lawfully present in the United States would be involuntarily disenrolled from MA, Part D, and cost plans, based on the date on which they lose their lawful presence status. Under our proposal, disenrollments would have been effective the first of the month following the loss of lawful presence status, and the disenrollment process would follow the process currently set forth in the regulations for an individual who is no longer eligible to be enrolled in a plan. Such disenrolled individuals would continue to be considered entitled to Medicare Part A and (if enrolled) enrolled in Part B coverage, provided they continue to pay premiums, as applicable, but as noted payment of FFS claims would be denied based on unlawfully present status.

These proposed regulatory changes were intended to prevent an individual known not to be lawfully present in the United States from enrolling in a Part C, Part D, or cost plan and/or remaining enrolled in such a plan, meaning that payments would not be made to plans or by plans with respect to such individuals during that period. This policy was intended to facilitate compliance with 8 U.S.C. 1611. We proposed the following changes in the regulations to refine the eligibility requirements for the MA and Part D programs and give MA and Part D plans the ability to disenroll individuals who are not lawfully present in the United States:

- Sections 417.420, 417.422, 422.50, and 423.30 would be amended to add lawful presence or United States citizenship as eligibility criteria for enrollment in a cost, MA, or Part D plan.
- Sections 417.460, 422.74, and 423.44 would be amended to require the involuntary disenrollment of individuals from cost, MA or Part D plans if they lose lawful presence status.
- Conforming changes would be made to §§ 417.2, 422.1, and 423.1 to outline the authority for the aforementioned requirements, from 8 U.S.C. 1611 (Aliens who are not qualified aliens ineligible for federal public benefits).

We received the following comments on our proposals:

Comment: Overall we received general support for our proposal. Many commenters requested clarification about who would be responsible for verifying eligibility based on lawful presence. A few of these commenters stated specifically that CMS should verify this aspect of eligibility and that plans should not be expected or permitted to request proof of lawful presence from individuals. A commenter, who did not agree with the proposed change, expressed concern that plans do not have access to data to validate residency/lawful status for Medicare beneficiaries and requested what source would be used for status changes.

Response: We appreciate the support expressed by most commenters. We agree that CMS would have to provide lawful presence information to plans. In most cases, the DHS determines citizenship and lawful presence status and that information is passed to SSA. SSA also has mechanisms to address changes in lawful presence status reported by beneficiaries themselves or other third parties. CMS receives the lawful presence information from SSA after it completes its processes related to such changes in status. Then, we will notify the plan if an individual is not eligible for MA, Part D or cost plan enrollment based on lawful presence and the plan must either deny the enrollment request or process the involuntary disenrollment. Plans are not expected to independently determine lawful presence when processing the enrollment request, nor should they request proof of citizenship from the beneficiary or include lawful presence as an element on the enrollment form. We will notify plans of ineligibility due to unlawful presence, through the same administrative mechanisms currently utilized to notify plans about other

[2] Medicare Improperly Paid Providers Millions of Dollars for Unlawfully Present Beneficiaries Who Received Services During 2009 Through 2011 (A–07–12–01116), available at *http://oig.hhs.gov/oas/reports/region7/71201116.asp.*

involuntary disenrollments. Additionally, we will be providing more detailed information about the necessary processes and procedures in subregulatory guidance.

Comment: A few commenters suggested that we amend the regulations to require a notice for the beneficiaries if they are disenrolled for absence or loss of lawful presence status. Other commenters suggested revisions for the content of a disenrollment notice, specifically suggesting that it contain pertinent information regarding loss of eligibility for enrollment and related impacts to unlawfully present individuals.

Response: Under existing processes at SSA, individuals are notified of their potential change to lawful presence status and are provided an opportunity to be heard in advance of any final changes in status in SSA records (that is, before the information is transmitted to us [3]). We believe that this process by SSA provides adequate notification to the beneficiary and, at this time, CMS will not require an additional notice from the plan at the time of disenrollment. This policy on notification from the plan is similar to CMS processes and regulations for other involuntary disenrollments based on information from CMS,[4] but we will take into consideration the possibility of requiring notice in future rulemaking.

In our existing subregulatory guidance, MA, Part D and cost plans are strongly encouraged to send confirmation of disenrollment to members even when it is not required. We agree that a notice regarding the reason for involuntary disenrollment and the impact unlawful presence status has on the payment of Medicare services would reinforce the messages already provided by SSA, and CMS encourages plans to send such notices in this situation. Sending a confirmation of disenrollment would ensure that these beneficiaries understand the restrictions of their Medicare coverage as they transfer to the FFS program. We appreciate the suggested notice language provided by the commenters and will consider it as we establish a model notice in Chapter 2 and Chapter 17-Subchapter D of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Further, for instances where an unlawfully present individual is denied enrollment into a MA, Part D, or cost plan due to ineligibility, we currently require that the plan provide written notice of the denial.[5] We will consider the suggested language as we modify the existing model denial notices in these subregulatory chapters.

Comment: Several commenters expressed concern about the effective date of disenrollment if it is based on the date of loss of lawful presence status. Specifically, commenters suggested that involuntary disenrollments be prospective because the plan provides coverage on the reasonable assumption of eligibility to receive services. Further, commenters were concerned about the recoupment of capitation payments as a result of these retroactive disenrollments.

Response: In the proposed rule, we proposed that disenrollments would be effective the first of the month following the loss of eligibility to receive federal benefits because this is in line with the statutory requirement that individuals not receive federal benefits when they are not lawfully present in the United States. Operationally, we did not believe it was feasible to maintain enrollment in a Part C, Part D or cost plan for a period for which we would be required to recoup capitations retroactively. Therefore, we proposed a procedural mechanism to default enrollment for such individuals to Original Medicare, where the FFS payment exclusion policy would be applied. Any retroactive disenrollments would under our proposed approach result in recoupment of payments, as supported by existing regulations in §§ 417.464(a)(1), 422.308(f)(1), 423.315(f) and 423.343(a), which require CMS to retroactively adjust plan payments due to changes in enrollment status. At the time we made this proposal, it was consistent with the approach adopted under FFS Medicare, which also made retroactive recoupments in cases in which someone receiving Medicare benefits is determined not to have been eligible for them.

While we believed that this approach was the best way to implement our obligation to comply with PRWORA, in considering comments received on the proposal, we are reconsidering the issue of retroactive disenrollment. First, while our proposal was consistent at the time it was made with FFS policy on retroactive recoupments, we have revised that policy, based on section 1870 of the Act, and are now denying payments only prospectively. We are also aware of due process arguments that may apply to retroactive recoupment. Because, under our systems, retroactive disenrollment would automatically result in retroactive recoupment, and we are reconsidering the issue of whether such retroactive recoupment in the case of Part C, Part D and cost plans is appropriate, we are not finalizing the retroactive aspect of our proposal on disenrollment, and at this time are finalizing only the prospective period of disenrollment provided for in the proposed rule. We are moving forward with finalizing prospective disenrollment while reconsidering the issue of retroactive enrollment because we believe that prospective disenrollment should be put in place as soon as possible, both to implement the prohibition on benefit payments to individuals who are unlawfully present in the United States, and minimize the period of any potential retroactive recoupment in the event we decide at a future point to proceed with our original proposal to disenroll individuals retroactively.

Therefore, we are finalizing text different from our original proposal to make all disenrollments effective the first of the month following the loss of eligibility to receive federal benefits (that is, retroactively), and instead at this time will revise §§ 417.460(j), 422.74(d)(8), and 423.44(d)(8) to provide that disenrollments are effective the first of the month following notice by CMS that the individual is ineligible. This adjustment will ensure that CMS establishes the required mechanisms to permit prospective enrollment into MA, Part D and cost plans only for individuals eligible to receive Medicare benefits, and prospectively disenroll beneficiaries currently enrolled in plans as of this provision's applicability date.

As discussed in the proposed rule, the OIG noted in a January 2013 report that CMS needed to increase efforts to detect and prevent improper payments for Medicare services rendered to unlawfully present beneficiaries. In a subsequent report published in October 2013 [6], the OIG specifically recommended that CMS develop and implement controls to ensure that Medicare does not pay for prescription drugs for unlawfully present beneficiaries and that CMS do so by

[3] Social Security Administration Program Operations Manual System (POMS) RS 00204.010 Lawful Presence Payment Provisions and RS 00204.080 Postentitlement Suspension—Alien is no Longer Lawfully Present.

[4] Notices are required from the plans in cases of certain disenrollments. See 42 CFR.417.430, 422.74(c), and 423.44(c).

[5] Notices are required from the plans in cases of enrollment denials. See 42 CFR 417.430(b)(3), 422.50(e)(3), and 423.32(d).

[6] Medicare Improperly Paid Providers Millions of Dollars for Prescription Drugs Provided to Unlawfully Present Beneficiaries During 2009 Through 2011 (A–07–12–006038) (*http://oig.hhs.gov/oas/reports/region7/71206038.pdf*).

preventing enrollment of unlawfully present beneficiaries, disenrolling any currently enrolled unlawfully present beneficiaries, and automatically rejecting PDE records submitted by sponsors for prescription drugs provided to this population. We believe that prospective disenrollments address these recommendations, and serve as an initial step in ensuring that payment is made for only individuals eligible to receive services. As we move forward with implementation, we will carefully consider enrollment retroactivity and resulting recoupments, and if determined appropriate, propose changes or additional regulations through future rulemaking.

Lastly, we believe it is important to note while CMS is dependent upon the data received by the DHS through SSA, we ensure that the data are passed to the plans within 24 hours of receipt via the Daily Transaction Reply Report. In addition, we will work with these agencies to explore options for receiving these data in the most efficient and timely means possible.

Comment: A few commenters suggested that beneficiaries who are involuntarily disenrolled due to unlawful presence should be entitled to appeal their disenrollment.

Response: We thank these commenters for their suggestion to ensure that affected individuals have the opportunity to appeal the reason for their disenrollment from their plan. Currently, there is no right of appeal associated with MA, Part D or cost plans eligibility or enrollment, because enrollment in such plans is voluntary and involuntary disenrollments are not considered initial determinations as outlined in § 405.924(a). We reiterate that individuals disenrolled from MA, cost or Part D plans are defaulted to coverage under FFS Medicare unless Parts A and B entitlement and enrollment ends under 42 CFR part 406, subpart B and §§ 406.28 and 407.27. However, individuals who are subject to involuntary disenrollment from these plans due to lawful presence status are provided with due process prior to any change in their status by SSA and exchange of any data to CMS and loss of MA, Part D, or cost coverage (or denial of claims for an individual enrolled in the FFS program).

These individuals are provided with advance notification in writing of the possible status change and an opportunity to respond or submit the necessary documentation to maintain a lawful presence status under existing SSA processes.[7] Following a status change to lawful presence status by SSA, individuals are also provided an opportunity to appeal the determination as outlined in 20 CFR 404.902. SSA has existing processes to accept and review evidence from individuals who believe that they are lawfully present and to update SSA's records. These individuals, based on the date of regaining lawful presence status, would then have the opportunity to re-enroll and, in certain cases of government error, be reinstated into their former plans. As we prepare for implementation of this rule, we intend to consider these issues carefully to ensure beneficiaries are notified of the consequences to Medicare coverage that flow from changes in lawful presence status.

Comment: A few commenters requested that CMS put in place a special enrollment period (SEP) for individuals who are disenrolled from their MA or Part D plan based on unlawful presence and then later regain lawful presence status and wish to re-enroll in a Part D or MA plan. In addition, commenters requested that if an individual is involuntarily disenrolled from a Part D plan due to unlawful presence, and that individual later regains lawful presence status, the individual should not be subject to a late enrollment penalty (LEP) for the period of time they did not have Part D (or other creditable) coverage.

Response: We appreciate the concern expressed by the commenters about ensuring access to Medicare coverage and limiting financial consequences after a beneficiary gains, or regains, lawful presence status. Medicare beneficiaries may incur an LEP for Part D if there is a continuous period of 63 days or more at any time after the end of the individual's Part D initial enrollment period (IEP) during which they were eligible for, but did not enroll in, a Medicare Part D plan and were not covered under any creditable prescription drug coverage. If an individual is disenrolled from a Part D plan because of loss of lawful presence status, this is not considered a break in creditable prescription drug coverage because the individual is not eligible for Part D benefits during this time. Therefore, an LEP would not apply for that period of time. If an individual regains lawful presence status and, as a result, also regains Part C and/or Part D eligibility, the individual does not get a new IEP, but we acknowledge that an SEP is warranted to allow these individuals to enroll in an MA or Part D plan, including a cost plan's optional supplemental Part D benefit, under §§ 422.62(b)(4) and 423.36(c)(8)(ii) if the individual is not otherwise eligible for an SEP. The change in lawful presence status of an individual necessary to trigger a change in eligibility under these rules is extraordinary enough to justify the provision of a SEP under the existing authority of §§ 422.62(b)(4) and 423.36(c)(8)(ii), even without the additional concern that late enrollment penalties could be incurred by beneficiaries who are not able to enroll following their regained eligibility for Part D coverage. The parameters of this SEP will be outlined in subregulatory guidance. However, we note that in this scenario if the newly eligible individual does not take advantage of the SEP to enroll in a plan providing Part D coverage and has no other creditable prescription drug coverage, the individual may be subject to an LEP for any future Part D enrollment.

Comment: A few commenters provided feedback regarding the proposed use of the term ''qualified alien'' in the proposed text at §§ 417.422, 417.460, 422.50, 423.1, 423.3, and 423.44. Commenters suggested changing it to more accurately reflect the lawful presence eligibility requirements for Medicare benefits outlined in 8 CFR 1.3 so that we are not restricting eligibility to only qualified noncitizens to enroll in or maintain their benefits. The broader term ''lawfully present'' for this purpose includes ''qualified aliens'' as well as several other categories of non-citizens, whereas the proposed terminology only included ''qualified aliens'' which is one of the subcategories included in those lawfully present.

Response: We agree with the concern raised by commenters and are finalizing the regulatory language at §§ 417.422(h), 417.460(b)(2)(iv), 417.460(j), 422.50(a)(7), 422.74(b)(2)(v), 422.74(d)(8), 423.1(a)(3), 423.30(a)(1)(iii), 423.44(b)(2)(iv), and 423.44(d)(8) without references to qualified aliens; the final regulatory language encompasses all individuals who are lawfully present consistent with 8 CFR 1.3.

After consideration of the public comments received, we are finalizing the policies and regulations text as proposed, with the following exceptions:

- At §§ 417.422, 417.460, 422.50, 423.1, 423.3 and 423.44, we are deleting the term ''qualified alien.''

[7] Social Security Administration, Policy and Operations Manual System (POMS): RS 00204.010. Lawful Presence Payment Provisions, GN 03001.005 Notice Requirements for Title II Due Process Actions, and GN 03001.015 Notices Required Before And After Taking a Title II Adverse Action.

• At §§ 417.460(j), 422.74(d)(8), and 423.44(d)(8), we are modifying the effective date of the involuntary disenrollment to be the first of the month following notification by CMS.

• At § 417.460, we are redesignating paragraph (b)(2)(iv) as paragraph (b)(2)(v) and finalizing the provision establishing a lack of lawful presence as a basis for disenrollment from a cost plan at paragraph (b)(2)(iv).

3. Part D Notice of Changes (§ 423.128(g))

Section 1860D–4(a) of the Act requires Part D sponsors to disclose to beneficiaries information about their Part D drug plans in standardized form. The Act further directs Part D sponsors to include, as appropriate, information that MA organizations must disclose under section 1852(c)(1) of the Act, which includes a detailed description of benefits. (In guidance, we refer to the document containing this information and delivered to beneficiaries as the Evidence of Coverage (EOC).) To make informed decisions, enrollees need to understand how their benefits, including premiums and cost sharing, would change from one year to the next, should they reenroll in the same plan. (In guidance, we refer to the documents containing this information and delivered to beneficiaries as the Annual Notice of Change (ANOC).) Enrollees also need to be aware of changes that may take place during the course of the year as well. Part D regulations currently do not include language found in the Part C regulations at § 422.111(d) requiring notice of changes to the plan to be provided to CMS for review pursuant to procedures for marketing material review and to all enrollees at least 15 days prior to the annual coordinated election period. Given that guidance applicable to both programs discusses notice of changes, we proposed to require, for Part D, delivery of an ANOC.

Specifically, we proposed to adopt in Part D, with modifications, the language contained in § 422.111(d). As is the case with the MA regulation, proposed § 423.128(g) would require that Part D sponsors submit their changes to us under the procedures contained in subpart V of part 423, and, for those changes taking effect on January 1, provide a notice of changes to all enrollees 15 days before the beginning of the annual election period. While part 422 requires a minimum of 30 days notice before the effective date for all other changes, we proposed at § 423.128(g)(3) that Part D sponsors remain subject to all other notice requirements specified elsewhere in the Part D regulations. Our proposal reflected a programmatic difference between Parts C and D: Under Part D it is not unusual for access to drugs listed on a plan's formulary to change during the course of a year. Changes can include changes to formulary status, tier placement, and utilization management or other restrictions. It is vital that beneficiaries currently taking a drug receive timely notice before such changes take place in order that they can decide whether to, for instance, change drugs or request an exception to cover the drug. Accordingly, our regulations currently specify when sponsors must provide notice of these kinds of changes. Our proposal to require the delivery of an ANOC was not intended to disrupt or change those existing notice requirements.

In the proposed rule, we also took the opportunity to comment on the particular importance for Part D sponsors to provide notice in the ANOC of any changes they are making that will affect the amount of cost sharing that enrollees must pay for each drug belonging to a specific tier. As has been articulated in guidance for several years, we expect that sponsors will provide notice of such changes to all enrollees, including enrollees moved to a consolidated plan. Generally, sponsors compare information such as cost sharing for the same plan from one year to the next in the ANOC. However, comparing information for the same plan would not benefit individuals moved from one plan to another. For instance, when a sponsor crosswalks members from a non-renewing plan to a consolidated renewal plan from one year to the next, cost sharing may change at the drug-tier level. An enrollee who previously had zero cost sharing for all covered Part D drugs within the preferred generic tier may find that the consolidated plan now requires copays for drugs in that tier depending on how many months' supplies he or she orders, and whether he or she obtains those drugs at a retail level pharmacy or through mail order. We expect that enrollees will receive ANOCs that clearly compare the non-renewed and consolidated plans' copayments or coinsurance for all drugs within each tier.

We received the following comments on this proposal and our response follows:

Comment: Commenters supported this proposal for informing beneficiaries about their coverage options. Several pointed out that it was important and appropriate for CMS to communicate cost-sharing changes through the Part D ANOC in addition to formulary information. One commenter urged us to perform ongoing monitoring of formulary changes including cost sharing to ensure they are justified and appropriately communicated to beneficiaries.

Response: We thank the commenters for the support. While we appreciate the concerns about monitoring, we did not propose any changes with respect to monitoring of formulary changes, and we decline to address that issue in this final rule.

Comment: Several commenters observed that, while many Part D sponsors already provide this annual notice under CMS guidance, they thought it important that this requirement be made explicit through rulemaking. In contrast, a commenter noted that developing a Part D ANOC was not necessary because of information provided through other material. Another commenter suggested that, if possible, Part D information should be incorporated into the Part C ANOC to avoid the potential for confusion, missing information, and duplicate costs.

Response: We thank the commenters for the support and can confirm that our goal in revising § 423.128(g) is to codify existing guidance. Our existing model ANOC includes sections on both Parts C and D, and CMS produces nine standardized model ANOCs and EOCs for all plan types.

Comment: A commenter requested that CMS confirm that this provision would merely codify existing guidance and would not necessitate any changes in practice for Part D sponsors that already deliver ANOCs that address plan changes consistent with existing CMS guidance.

Response: Section 423.128(g) will not affect current practice for Part D sponsors that that already deliver ANOCs consistent with our model notices.

Comment: A few commenters pointed out that finalizing this revision would add costs due to increased printing and administration requirements, with one commenter noting premiums could possibly increase.

Response: We disagree. Because we did not propose here to change existing practices, but rather only to codify existing guidance, we do not believe the revision to § 423.128(g) will increase costs.

Comment: A commenter suggested that MA organizations and Part D sponsors be required to share ANOCs with LTC providers in plan networks to enable them to better coordinate and support the beneficiaries in making informed decisions when their health

conditions limit their ability to effectively communicate about their coverage. Another commenter suggested that we add language to the Part D ANOC advising beneficiaries for the future that it was important to review the new contract year formulary.

Response: We appreciate these suggestions and will take them into consideration for the future for our guidance on the model notices. However we decline to accept the commenter's suggestion to add this to the regulation text because, as previously noted, our proposal was intended to codify existing guidance.

After review of the public comments received, we are finalizing this provision as proposed without modification.

4. Business Continuity for MA Organizations and Part D Sponsors (§ 422.504(o) and § 423.505(p))

A variety of events ranging from power outages to disasters and warnings of disasters can disrupt normal business operations, and when these events occur it is important that MA organizations and Part D sponsors have a plan to ensure beneficiary access to health care services and drugs. Sections 1852(d) and 1860D–4(b) of the Act, respectively applicable to Parts C and D, establish access to services and covered Part D drugs as a core beneficiary protection. After Hurricane Sandy it became apparent that a few entities, particularly those with operational centers and/or information technology (IT) resources physically located in the affected areas, did not have consistent continuity plans or back-up systems and processes to ensure ongoing coordinated deployment of critical staff to alternate locations.

Sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act authorize the Secretary to adopt additional contract terms for, respectively, MA organizations and Part D sponsors, including section 1876 cost contracts and Programs of the All-Inclusive Care for the Elderly (PACE) organizations that provide qualified prescription drug coverage, that are not inconsistent with Parts C and D, respectively, of Title XVIII of the Act, when the Secretary finds it necessary and appropriate. While a limited number of beneficiaries were affected by problems on the part of a small number of entities as a result of Hurricane Sandy, we have a goal of consistent disaster response for plans within the scope of our proposal. Therefore, we proposed that all MA organizations and Part D sponsors limit the impact on beneficiaries of unavoidable disruptions and establish a plan to ensure rapid restoration of operations. The scope of our proposal included section 1876 cost contract and PACE organizations that provide qualified prescription drug coverage under Part D. We also proposed to add contract provisions to require that MA organizations and Part D sponsors develop and maintain business continuity plans in order to better anticipate the types of disruptions that could occur and implement policies and procedures to reduce interference with business operations. Our proposal was based on a belief that such planning is appropriate and necessary to better ensure that Medicare beneficiaries have access to the care and coverage contemplated by the statute.

The proposed provisions, in §§ 422.504(o)(1) and 423.505(p)(1), would require that every MA organization and Part D sponsor develop, maintain, and implement a business continuity plan that meets certain minimum standards. In §§ 422.504(o)(1)(i) and 423.505(p)(1)(i), we proposed that the business continuity plan assess risks posed to critical business operations by disasters and other disruptions to business as usual; in the preamble, we clarified that our proposal would apply regardless whether the risks, disasters or disruptions be natural, human, or environmental. In paragraph (1)(ii) of §§ 422.504(o) and 423.505(p), we proposed to require MA organizations and Part D sponsors to mitigate those risks through a variety of strategies, at a minimum by: (1) Identifying events (triggers) that would activate the business continuity plan; (2) developing contingency plans to maintain the availability and, as applicable, the confidentiality of hard copy and electronic essential records, including a disaster recovery plan for IT and beneficiary communication systems; (3) establishing a chain of command, which would better ensure that employees know the rules of succession; (4) creating a communications plan that includes emergency capabilities and means to communicate with employees and third parties; (5) establishing procedures to address management of space and transfer of employee functions; and (6) establishing a restoration plan with procedures to transition back to normal operations. Finally, we also proposed, in §§ 422.504(o)(1)(ii)(G) and 423.505(p)(1)(ii)(G), that the business continuity plan comply with all applicable federal, state, and local laws. In light of the nature of the records an MA organization or Part D sponsor would have in its possession, we proposed to emphasize continuing compliance with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule (45 CFR parts 160 and 164, subparts A and C) by including a cross-reference to those requirements in paragraph (1)(ii)(B)(2) of each proposed regulation. These areas of responsibility are essential to continuing the business operations that allow beneficiaries to access health care services and covered Part D drugs.

To better ensure that a business continuity plan works as a practical matter, we next proposed in §§ 422.504(o)(1)(iii) and (iv) and 423.505(p)(1)(iii) and (iv) to require that on an annual basis, each MA organization and Part D sponsor test and revise the plan as necessary, and train employees on their responsibilities under the plan. Proposed §§ 422.504(o)(1)(v) and 423.505(p)(1)(v) would require that MA organizations and Part D sponsors keep records of their business continuity plans that would be available to CMS upon request.

We stated our belief that the broad list of areas that we proposed to cover as part of business continuity plans were not new to MA organizations and Part D sponsors. We stated these topics typically appear in standard business continuity plans and that we also were building on some requirements that already existed under federal and state laws. For instance, with respect to electronic protected health information, health plans have long had to comply with the contingency plan requirements found in the HIPAA Security Rule. We indicated our goal was to provide a list broad enough to align with the business contingency plans that we believed most, if not the vast majority, of MA organizations and Part D sponsors already had in place.

In contrast to the aforementioned list of broad content requirements, we stated that the need to protect beneficiary access required a prescriptive approach for some functions. In proposed §§ 422.504(o)(2) and 423.505(p)(2), as part of the proposal that essential functions must be restored within 24 hours of failure (whether due to disaster, emergency, or other disruption), we identified what we believed to be the minimum essential functions for both MA and Part D plans: Benefit authorization, if authorization requirements have not been waived, and claims adjudication and processing; an exceptions and appeals process; and call center operations. We stated that given the mandate of the Act to ensure beneficiary access to health care and

covered Part D drugs and the inability of many beneficiaries to pay for services or drugs without the Medicare benefit, we believed that the operations listed in the proposed regulations were the most essential operations because they directly supported the provision of Part C and D benefits. We stated that they ensured immediate electronic communication on the availability and extent of Part C and D benefits and also provided support that makes it more likely that Medicare benefits will be appropriately and timely provided (for example, by providing telephone assistance to beneficiaries with questions on how to obtain benefits and maintaining a forum in which beneficiaries can challenge benefit denials). We observed that without real time provision of Medicare benefits, beneficiaries might not pay for the entire cost of the services or drugs and therefore go without necessary treatment.

We also proposed a list of the operations that we believed were essential operations that had to be restored in a rapid time frame. We intended our proposed deadline of the proposed 24 hours to be the outside limit and at that time articulated an expectation that MA organizations and Part D sponsors restore operation of essential functions as soon as possible but not later than 24 hours after they fail or otherwise stop functioning as usual. We stated the clock would begin running in cases of total failure (for example, a computer or telecommunications system crashes or stops working after disruption of the power supply) and also when significant problems occur (for example, a central database is corrupted).

We stated that the need to ensure correct claims adjudication and benefit administration of health care services and drugs is no less acute during disasters or other emergencies, and that such disruptions in one part of the country might disable MA organization and Part D sponsor systems that affect enrollees in other regions. We noted that beneficiaries in those unaffected areas who are denied health care or drug benefits (that is, access to drugs or reimbursement for claims paid out of pocket) before the disruption took place should not be denied the right to immediately challenge those denials or to learn timely the resolution of earlier challenges. As proposed, §§ 422.504(o)(2)(i) and 423.505(p)(2)(i) identified benefit authorization (if not waived) and claim adjudication and processing as essential functions which had to be operational within 24 hours. Our proposal required restoration of those operations for services rendered at a hospital, clinic, provider office, or at the point of sale for Part D covered drugs. We also stated in the proposed rule that this function was essential for both MA and Part D plans.

In addition, we proposed standards specific to Part D sponsors in § 423.505(p)(2)(ii) and (iii) to ensure that a beneficiary who presents at a pharmacy with an appropriate prescription for a covered Part D drug during a disruption would be more likely to receive the drug at the point of sale. The first three prongs under proposed § 423.505(p)(2) classified as essential the following functions: (i) Authorization, adjudication, and processing of pharmacy claims at the point of sale; (ii) administration and tracking of enrollee's drug benefits in real time, including automated coordination of benefits with other payers; and (iii) provision of pharmacy technical assistance. We noted these essential tasks entail numerous subfunctions. For instance, we stated that Part D sponsors would need to restore within the 24 hour return to operations (RTO) all computer and other systems that meet all privacy and security requirements in order to communicate to pharmacies information about topics including: coverage under Part D and the specific plan; cost-sharing and deductibles; any restrictions such as prior authorization, step therapy, or quantity limit edits; and coordination of benefits from other insurers and any low income subsidies. Additionally, we noted that the sponsor would need to undertake a concurrent drug utilization review (DUR) to address, for instance, safety issues, as well as restore its pharmacy help desk to provide prompt answers to any questions pharmacies might have. (For more detail on some of these functions and sub-functions, as related to Part D, please see section III. A.10, ''Requirement for Applicants or their Contracted First Tier, Downstream, or Related Entities to Have Experience in the Part D Program Providing Key Part D Functions'' of the May 23, 2014 final rule (79 FR 29867)).

Proposed §§ 422.504(o)(2)(ii) and 423.505(p)(2)(iv) each classified as an essential operation an enrollee exceptions and appeals process including coverage determinations. Under these proposed rules we specified that, within 24 hours of failure, MA organizations and Part D sponsors would need to restore all IT and workforce support necessary to maintain the ''safety net'' that ensures beneficiaries the rights to appeal or to seek a formulary exception.

Finally, for both MA organizations and Part D sponsors, we proposed that the operation of the call center be an essential function which must be restored within 24 hours. We stated that by classifying operation of the call center as essential, proposed §§ 422.504(o)(2)(iii) and 423.505(p)(2)(v) would ensure that beneficiaries could receive the information necessary to find out where they need to go to access benefits and learn about any special rules that might apply (for example, whether pre-authorization requirements are waived or beneficiaries can obtain benefits at out-of-network providers or pharmacies). We stated that enabling a beneficiary who has just been denied Part D coverage at his or her usual pharmacy to call immediately and speak to a customer service representative while still standing in that pharmacy could ensure that he or she obtained drugs appropriately covered by his or her Part D plan before returning home or moving to a safer area.

Furthermore, in the proposed rule we stated that because it might be difficult during a disaster to get to a provider's office or a pharmacy, we believed it was important that benefit authorization, claims adjudication, and call center operations be restored within 24 hours after failure. While our proposed provisions required both MA organizations and Part D sponsors to coordinate their workforce, facilities, and IT and other systems support to meet a 24 hour RTO, in the preamble to the proposed rule we noted our belief that the vast majority of MA organizations and Part D sponsors already met, or would be able to meet, this requirement with their current resources, based on our knowledge of the industry and as evidenced by the lack of widespread problems with MA organization and Part D operations after recent natural disasters in different parts of the country. We observed that MA organizations and Part D sponsors would not be required to take any prescribed specific actions (for example, there was no requirement for redundant systems located at certain distances apart) to meet these standards. Rather, we stated that the proposed 24-hour RTO would allow MA organizations and Part D sponsors the flexibility to continue to seek their own disaster preparedness solutions (for instance, vendor sites or functions spread across facilities).

We stated that our goal in proposing a contractual requirement for business continuity plans was to better ensure beneficiary access to health care services and Part D drugs during disasters and other interruptions to

regular business operations, and we viewed prior planning as essential to achieving this goal. We specifically solicited comments regarding which functions should be identified as essential operations and the 24-hour timeframe for RTO and stated that we would appreciate any information unique to the role of MA organizations and Part D sponsors.

We received the following comments on these proposals and our response follows:

Comment: Some commenters strongly supported the proposed provision and noted that it was absolutely critical that MA organizations develop and test business continuity plans to ensure that beneficiary needs are met and commended CMS for its commitment to ensure beneficiary access to Medicare benefits. A number of commenters specifically approved that part of the proposed regulation that set forth minimum standards. Additionally, several commenters, including some who did not support the specific requirements of the proposed provision, agreed that there was a need for ''robust'' business continuity plans.

Response: We thank those commenters who support the proposal in its entirety or approved the general outline of minimum requirements, as well as those who recognized there is a need for MA organizations and Part D sponsors to have business continuity plans.

Comment: Noting that CMS acknowledged in the preamble there were relatively few problems in the past, some commenters stated that industry practices were adequate and questioned the need for detailed provisions that classified certain functions as essential which had to be restored within a 24-hour RTO deadline. A few commenters pointed to the fact, also acknowledged by CMS in the preamble, that the requirements overlapped with other existing federal, state, and local requirements such as the HIPAA Security Rule and stated that they saw no need for an additional layer of regulation. In contrast, another commenter stated that developing a business continuity plan should not be overly burdensome because the HIPAA Security Rule already requires development of such a plan.

Response: We appreciate the fact that, as far as we are aware, only a limited number of beneficiaries experienced problems as the result of inadequate continuity planning in the wake of Hurricane Sandy. However, there were some beneficiaries who were unable to access benefits, and contingency planning might have prevented some of those problems. Having a business continuity plan to prepare for business disruptions is an established business practice; the fact that most MA organizations and Part D sponsors successfully handled the disaster does not excuse those entities that did not.

We do not believe that requiring a business continuity plan is imposing an unnecessary level of regulation. However, we would like to clarify that HIPAA requirements are distinct from our business continuity provision. As we noted previously, with respect to electronic protected health information, health plans have long had to comply with the contingency plan requirements found in the HIPAA Security Rule. Referencing this rule created no additional burden.

Comment: Commenters stated that the regulation was significantly more detailed than necessary. While some commenters pointed to concerns regarding paragraph (1) of §§ 422.504(o) and 423.505(p) which lists basic minimum requirements (addressed later in this section), most commenters noted concern with paragraph (2) of §§ 422.504(o) and 423.505(p) which identified as essential specific functions and required that MA organizations and Part D sponsors restore them within 24 hours of failure or loss of function.

- The majority of commenters opposed the requirement that MA organizations and Part D sponsors restore essential functions within 24 hours, with several stating this was not feasible. Many commenters noted that because catastrophes are by their nature hard to predict, out of the control of MA organizations and Part D sponsors, and result in major disruptions that have the potential to last for weeks (for instance, power outages), a 24-hour RTO deadline would hamper the flexibility of MA organizations and Part D sponsors to prioritize. A commenter suggested that we institute a ''force majeure'' clause to provide relief for causes beyond the control of MA organizations and Part D.
- Commenters indicated that they generally agreed with CMS that the emphasis should be on quickly getting care to those beneficiaries who need it, and there was some consensus that providing drugs and services at point-of-sale (POS) should remain an essential function. Several commenters observed that, consistent with industry standards, Part D sponsors were generally able to restore the systems necessary to allow beneficiaries to obtain drugs within approximately 24 hours. For instance, a commenter identified benefit authorization, claims adjudication, and pharmacy services as higher priorities. Some commenters specifically identified call center services as time-sensitive functions requiring a 24-hour recovery.
- However, there was no clear consensus on the specific functions that should be considered essential or even how to prioritize among all of them. For instance, a commenter noted normal appeals would fall into a longer category than 24 hours recovery, but that expedited appeals might possibly fall within the 24 hour time line. Several commenters suggested that different functions would require different RTO time frames. Several commenters mentioned a 72-hour timeframe, with one noting it restored functions less critical for health and safety within 72, rather than 24, hours.
- In evaluating essential functions, a number of commenters distinguished between the Part C and D programs. Commenters observed, for instance, that provider payments are not a 24-hour critical function for MA plans since payment is allowed to be made within 30 days and that in a disaster or emergency MA organizations should not be required to prioritize claims processing for services already rendered. In contrast, a few commenters agreed that the 24-hour restoration requirement could be applied to Part D point-of-sale claims that require immediate adjudication.

Response: These commenters persuaded us that we need to build more flexibility into our business continuity plan requirements for RTO for essential functions and we are accordingly finalizing the regulation with changes from our proposal. In paragraph (2) of §§ 422.504(o) and 423.505(p), we are providing that MA organizations and Part D sponsors must plan to restore essential functions within 72, rather than 24, hours after any one of the essential functions fail or otherwise stop functioning as usual. As discussed in more detail later in this section, we also finalize regulation text to clarify that we require MA organizations and sponsors to ''plan to'' restore essential functions within the 72-hour time period, rather than guarantee complete restoration within the time frame. Given the lack of a clear consensus on how to prioritize all essential functions, we believe that this will provide MA organizations and Part D sponsors with the flexibility the commenters advocated, and still address our concerns about planning to better ensure beneficiary access to the Medicare benefit.

However, we underscore that although we are finalizing a more flexible regulatory mandate, we expect that Part D sponsors will plan for a 24-

hour RTO deadline for POS transactions. We are concerned that beneficiaries who are not able to access their Part D drug coverage may in fact suffer adverse health effects. Our decision not to explicitly require a plan for a 24-hour restoration for POS drug transactions is informed by the fact that commenters suggested that a 24-hour RTO for POS transactions is an industry standard already generally met, and that relatively few problems were reported in the aftermath of recent disasters. We want to ensure that that track record not only continues but improves. We will continue to closely monitor the timing of POS transaction in the aftermath of disasters, emergencies, and other disruptions and take any necessary actions. We also will revisit the regulation if necessary.

We also agreed with commenters that there are distinctions between the Part C and D programs relative to identifying what services are of the highest priority for speedy restoration. For instance, beneficiaries need to know whether they have Part D Medicare coverage at the POS because usually they rely on the benefit to obtain prescription drugs. For most beneficiaries, such claim denials may mean they leave pharmacies without medications or pay out-of-pocket for costs that are their plans' responsibility. In contrast, this is often not the case for Part C health care services. Provision of Part C services is not so closely tied to plan authorizations and a provider may not bill the MA organization for services until days or weeks after the service is furnished. Thus, because beneficiary health and safety would not be put at risk by failure of Part C claims processing and appeals processes, we agree with the commenters that those systems are not essential functions to which the 72-hour timeframe would apply. Furthermore, as finalized in section II.E.9. of this final rule (MA Organization Responsibilities in Disasters and Emergencies (§ 422.100)), beneficiary access to health care services is protected in the more limited circumstances of disasters and public health emergencies and we believe that provision, in conjunction with § 422.504(o)(2), ensures, to the extent possible, that beneficiaries enrolled in MA organizations will have continued access to needed health care services when there are disruptions to normal business operations.

Accordingly we are finalizing § 422.504(o)(2) to define as essential services, for Part C purposes, benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service instead of the broader requirement that was proposed. This final rule text would include benefit authorization to the extent that members and providers contact the MA organization to request such authorizations even when the MA organization has waived that requirement.

Similarly, we agree that restoration of Part C claims processing and appeals processes are not essential functions in that beneficiary health and safety is not put at risk by a failure of those systems that lasts for longer than 72 hours. We agree with the commenters that in a disaster or emergency, MA organizations should not be required to prioritize claims for services already rendered, but we do not want beneficiaries to lose access to necessary treatment at provider offices. Accordingly, for Part C, we are no longer characterizing ''Operation of an enrollee exceptions and appeals process including coverage determinations'' as an essential function and are not finalizing that part of our proposal for § 422.504(o)(2).

Lastly, we agree with the commenters that characterized call center services as high priorities for both Part C and Part D plans. In a disaster or other emergency, normal procedures may be disrupted and beneficiaries need to be able to find out how and where they can obtain health care services and drugs by having contact with the plan.

In contrast, for Part D we plan to finalize § 423.505(p)(2) as proposed. We discussed the importance of the elements in more detail in the preamble to the proposed rule, but would like to note here that a beneficiary cannot obtain Part D coverage without benefits authorization, adjudication, and processing of drug claims at the point of sale. A pharmacy's inability to obtain, for instance, coordination of benefits information may affect the beneficiary's ability to obtain the drug as well; and pharmacy technical assistance is critical in case the dispensing pharmacy has questions. We also believe the operation of the enrollee exceptions and appeals process is essential—a beneficiary who has been denied Part D coverage will want to resolve quickly any issues so he or she can obtain the drug timely. Lastly, as previously noted, we believe call center operations are essential.

Comment: A commenter suggested there was a need for more detail in addition to that provided in the regulation as to exactly when the 24-hour clock would start and that CMS would, for instance, need to clarify if the clock would begin running when the disaster was declared or when it occurred. Another commenter suggested the proposed 24-hour RTO should begin running when the incident management team made the determination of action or after a specified amount of time after the disruption was reported.

Response: We believe that the language we proposed, namely that the clock will start running ''after any of the essential functions fail or otherwise stop functioning as usual,'' provides adequate direction to MA organizations and Part D sponsors. We are finalizing a clearly defined time period—72 hours (rather than the 24-hour time period proposed)—in which MA organizations and Part D sponsors must plan to restore essential operations. In contrast, we deliberately chose to provide more flexibility to MA organizations and Part D sponsors to determine the precise point at which the 72-hour clock starts running. Essential functions could fail in an infinite variety of ways depending on the circumstances and the systems and supports in place (for instance, claims processing systems might fail in different ways than operation of the exceptions and appeals process). We believe that MA organizations and Part D sponsors are in the best position to both learn about failures or disruptions in usual functions or the facts that might potentially cause them and, in the aftermath of such occurrences, gather as much information as possible internally and from outside sources (such as first-tier, downstream and related entities (FDRs) and local authorities and utilities). We will revisit this regulation if problems arise in the future.

Comment: A couple of commenters expressed concern that the requirement that MA organizations and Part D sponsors return functions to ''normal'' operations would not permit them to utilize temporary alternative workflows that could be more effective than normal business operations in preserving member access to care.

Response: We disagree with this conclusion. Our proposal does not require MA organizations and Part D sponsors to return immediately to normal operations but rather, views that as an ultimate goal in an ongoing transition process. Paragraph (1)(ii) of §§ 422.504(o) and 423.505(p) requires MA organizations and Part D sponsors to create a mitigation strategy to ''prioritize the order in which to restore [essential and] other functions to normal operations'', while paragraph (1)(ii)(F) of §§ 422.504(o) and 423.505(p) requires MA organizations and Part D sponsors to ''[e]stablish a restoration plan including procedures to transition to normal operations.'' Additionally, we do not define ''normal operations.'' In

fact, depending on the severity of a disaster or emergency, ''normal operations'' certainly might not be operations performed exactly the same as they were before the event. We do not prescribe when or how normal functions are performed; an MA organization or Part D sponsor may achieve a comparable level of performance (for example, in terms of appeals being heard on a timely basis at the same rate as before the disaster) and consider normal operations achieved even if different personnel or offices now perform those functions. We view ''normal operations'' as an operational level at which MA organizations and Part D sponsors are able to administer the benefit correctly and fulfill contract requirements.

Comment: A commenter stated that the proposed provisions were inconsistent with Executive Order 13563 which requires that proposed rules specify performance objectives rather than the behavior or manner of compliance that regulated entities must adopt.

Response: We disagree with this commenter. The first part of our proposed provisions simply lists basic areas that business continuity plans must cover. We also view as performance objectives the list of essential functions for which we require MA organizations and Part D sponsors to plan a 72-hour RTO. As revised, the regulation requires that each entity plan to restore those functions that directly support the timely provision of Part C and D Medicare benefits to beneficiaries. We leave it to the MA organizations and Part D sponsors to determine the manner by which they plan to meet these requirements timely after a failure occurs.

Comment: Commenters took issue with the costs associated with the proposal. A number of commenters expressed concerns that we were requiring continuous service which would give rise to enormous costs to create systems redundancy, while several commenters were concerned about the cost of testing IT systems on an annual basis.

Response: Although we believe the proposed regulation was clear in paragraphs (1)(ii)(B)(*1*) of §§ 422.504(o) and 423.505(p) that we do not expect plans to be able to maintain continuous service under all circumstances, we are revising both of these regulation paragraphs in this final rule to clarify the language that we believe caused this confusion. We are revising the language in the proposed paragraph (1) of §§ 422.504(o) and 423.505(p) to require MA organizations and Part D sponsors to plan to restore business operations following disruptions, rather than plan to continue business operations during disruptions.

To clarify, we do not expect MA organizations and Part D sponsors to prevent any disruptions on an absolute basis but rather to plan to ensure operations are restored as best they can when business operations fail. It is understood that disasters, emergencies, and other events may cause severe disruptions outside of the control of MA organizations and Part D sponsors; the reason we are requiring business continuity plans is to ensure that MA organizations and Part D sponsors are better equipped to handle those problems when they occur.

Additionally, proposed §§ 422.504(o)(2) and 423.505(p)(2) required that MA organizations and Part D sponsors ''restore'' essential functions within the specified timeframe, which we believe raises the same concerns expressed by the commenter. We want to make it clear that the actual restoration of essential functions within 72 hours is the goal of the business continuity plan, not a requirement that is to be met in all circumstances. Accordingly, the regulation is being finalized to require that MA organizations and Part D sponsors plan to restore essential functions within the 72-hour time period. The business continuity plan must be designed with this 72-hour period as a deadline.

As to the commenters' concern about the cost of annual IT training, paragraph (1)(iii) of §§ 422.504(o) and 423.505(p) requires MA organizations and Part D sponsors to test and update the business operations continuity plan on at least an annual basis. This broad description does not detail specific kinds of testing but relies upon MA organizations and Part D sponsor discretion to adequately test and update the business continuity plan. This would include determining exactly what must be tested and how such testing must occur.

Comment: A commenter expressed concern that the rule would require annual training for ''all'' employees, which might not be necessary under all conditions.

Response: We agree that it is best left to MA organizations and Part D sponsors to determine which employees would most appropriately require annual training on the business continuity plan. We are finalizing the regulations to require annual training of appropriate employees rather than all employees, as well as making changes to make the language applying to both Parts C and D consistent. Specifically, we are removing the phrase ''all employees, including contract staff'' from § 422.504(o)(1)(iv) and ''all new and existing employees'' from § 423.505(p)(1)(iv), and replacing them both with ''appropriate employees''.

Comment: Several commenters suggested that our regulatory impact analysis (RIA) significantly underestimated costs. Concerns were raised about the high cost of creating systems' redundancy to avoid any disruption of processing of claims; one commenter mentioned that the requirement would necessitate spending millions of dollars. Another commenter mentioned that many business continuity plans currently in place for MA organizations and Part D sponsors would not meet requirements such as the restoration of essential functions within 24 hours. A commenter was concerned that the estimate did not take into account resources needed to ascertain the extent of damage and evaluate options.

Response: We believe that the modifications, clarifications, and comments discussed previously about this final rule address the vast majority of concerns raised about the RIA. We are also well aware of the major expense of creating redundant computer systems to ensure there is no interruption in claims processing—and repeat that we are not requiring MA organizations and Part D sponsors to absolutely ensure that systems never fail or to build redundant systems to avoid any potential failure. We are requiring that MA organizations and Part D sponsors plan to avoid such system and other failures and, in the event they do occur, to be prepared to recover essential functions within a certain timeframe. We appreciate that while contracting organizations may plan—even plan well—to avoid such disruptions and to recover from them within 72 hours, there may be scenarios in which a return of functionality for essential operations within the timeframe of paragraph (2) of §§ 422.504(o) and 423.505(p) is impossible . We also believe that providing the greater flexibility to plan for a 72-hour, rather than 24-hour, RTO for MA organizations and Part D sponsors should further alleviate concerns about high costs.

In this final rule, we also are revising the regulations to clarify that we require annual training of ''appropriate'' rather than ''all'' employees. As noted earlier, our requirement for annual testing of the business continuity plan does not specify exactly what must be tested or how such testing must be conducted. As to the last comment, MA organizations and Part D sponsors need to assess damages and evaluate alternatives

regardless of whether they have business continuity plans.

Additionally, we have revised our cost estimates to account for costs of what we believe will be, at most, minimal changes to existing business continuity plans. We base this on: (1) The fact that we believe most MA organizations and Part D sponsors with existing business continuity plans already cover the same broad list of areas we require in this rule; and (2) revisions to our rule that provide flexibility that enables most MA organizations and Part D sponsors to follow the same industry standards commenters suggested they currently follow. (See section IV. Regulatory Impact Statement of this final rule.)

Comment: A commenter stated that MA organizations and Part D sponsors could incur potentially very large additional costs to come into compliance with the new requirements which would amount to unexpected expenses that would unfairly count against a plan's administrative expenses on its medical loss ratio (MLR) calculation.

Response: Items that count as MLR are outside of the scope of this final rule. However, we note that this final rule will apply to all MA organizations and Part D sponsors and that we believe strongly that planning for the least disruption to operations and better provision of health care and drug benefits during disasters is an important function for insurance companies, and that such work will also benefit the MA organizations and Part D sponsors themselves.

Comment: Noting that they are confidential and contain blueprint information on processes and supporting resources, a commenter requested that rather than make business continuity plans available to CMS upon request, that CMS require an in-camera review of certain elements. In contrast, another commenter recommended that CMS review such plans as part of the Medicare Part D application process as well as via regular CMS compliance audits. A third requested whether there would be an audit element that focuses on business continuity plans.

Response: We appreciate the commenter's concerns about confidentiality. First, we would like to note that we are not requiring MA organizations and Part D sponsors to submit these business continuity plans and materials as a matter of course or to make such plans publicly available. Furthermore, if we do request these documents, we do not intend to voluntarily disclose them to any parties outside of the government. Under the Freedom of Information Act (FOIA), members of the public may request government records, which may include documents submitted to us. MA organizations and Part D sponsors may seek to protect their information from disclosure under FOIA by claiming FOIA exemption 4 and taking the appropriate steps—including labelling the information in question as ''confidential'' or ''proprietary.'' Furthermore, redaction of especially sensitive information is sometimes an option, depending on what information CMS needs and the nature of the information the organization seeks to redact. We will consider both compliance and confidentiality needs as we develop application and audit requirements related to this provision.

Comment: A commenter requested that CMS require PACE and long term care services and support providers (such as skilled nursing facilities (SNFs) and assisted living residences (ALRs)) to create plans that deal with natural and other disasters.

Response: As discussed in this final rule, the requirements in this regulation that are applicable to Part D sponsors also apply to 1876 cost contracts and PACE organizations that provide qualified prescription drug coverage. On December 27, 2013, we proposed regulations on emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers (78 FR 79082). The emergency preparedness requirements of that regulation would apply to PACE organizations in their capacity as providers and, as we noted earlier, the Part D proposed requirements apply to PACE organizations to the extent they function as Part D sponsors.

Both that proposed rule and this finalized Part C and D rule have the same goal of ensuring the least interruption to beneficiary health care and drugs as a result of disasters and emergencies by requiring entities to assess possible risks and lessen their impact through planning. However, this final rule applies to the entities providing coverage of the benefits (MA organizations and Part D sponsors), while the other rule, ''Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' would apply to entities directly providing the services. Specifically, this Part C and D rule applies to MA organizations and Part D sponsors to better ensure that beneficiaries enrolled in their plans have access in a timely manner to the Medicare covered items and services, supplemental benefits and prescription drugs. In contrast, the emergency preparedness rule would apply to both the Medicare and Medicaid programs and would require providers and suppliers to be adequately prepared to meet the direct health care needs of patients, residents, clients, and participants during disasters and emergencies.

Comment: Commenters expressed concerns that the proposed regulation did not take into account disparate circumstances. A commenter noted that MA organizations and Part D sponsors typically were located in the same area where members experiencing disasters or emergencies were living, while other commenters suggested the requirement would particularly burden smaller entities or entities with less experience that might, for example, need to contract with third parties to meet RTO obligations.

Response: We appreciate that different MA organizations and Part D sponsors will face different challenges during disasters and emergencies. However, we drafted broad areas of coverage to provide as much flexibility as possible to different entities. Given that emergencies and disasters are varied and unpredictable, we believe it would not be prudent for CMS to try and create different requirements based on different circumstances. We also believe that most of these concerns about costs and sufficient flexibility have been addressed through revisions or clarification of this proposed regulatory change.

Comment: A commenter stated that it was not aware of any reason that there should be different standards for the protection of Medicare beneficiaries during disasters than those generally applicable to the rest of the population.

Response: The treatment of individuals who are not Medicare beneficiaries is outside the scope of this regulation. However, we note that we are the steward of the Federal Trust Fund with direct authority over the Medicare program. Disasters, emergencies, and disruptions not only can limit beneficiary access to Medicare benefits, but they pose direct threats to the health of beneficiaries which in turn could create greater needs for health care services and drugs. Our core function is to ensure as best we can that beneficiaries are able to access their Medicare benefits; we believe the requirement that MA organizations and Part D sponsors establish business continuity plans that better enable them to deal with disasters is central to achieving this goal.

After consideration of the public comments received, we are finalizing our business continuity proposal with the following modifications as discussed and as follows:

- In §§ 422.504(o)(1) and 423.505(p)(1) we are replacing the phrase ''ensure the continuation of business operations during disruptions'' with the phrase ''ensure the restoration of business operations following disruptions''.
- In § 422.504(o)(1)(iv) we are replacing the phrase ''all employees, including contract staff'' with the phrase ''appropriate employees''.
- In § 423.505(p)(1)(iv), we are replacing the phrase ''all new and existing employees'' with the phrase ''appropriate employees''.
- In §§ 422.504(o)(2) and§ 423.505(p)(2), we are inserting the words ''plan to'' before the phrase ''restore essential functions'' in order that it reads ''plan to restore essential functions.'' We are also replacing the number ''24'' with ''72''.
- In § 422.504(o)(2)(i), we are replacing the phrase ''Benefit authorization (if not waived), adjudication, and processing of health care claims for services furnished at a hospital, clinic, provider office or other place of service'' with ''Benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service.''
- We are removing proposed paragraph (ii) of § 422.504(o)(2) (''Operation of an enrollee exceptions and appeals process including coverage determinations.'') and renumbering proposed paragraph (iii).

5. Efficient Dispensing in Long Term Care Facilities and Other Changes (§ 423.154)

We proposed changes to the rule requiring efficient dispensing to Medicare Part D enrollees in long term care (LTC) facilities. For background, section 3310 of the Affordable Care Act amended the Act to add a new paragraph (3) to section 1860D–4(c) of the Act. Section 1860D–4(c)(3) of the Act provides that the Secretary shall require Medicare Part D sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, such as weekly, daily or automated dose dispensing, when dispensing covered Part D drugs to enrollees who reside in an LTC facility in order to reduce waste associated with 30-day fills. The section states that the techniques shall be determined by the Secretary in consultation with relevant stakeholders.

After extensive consultation with stakeholders, in the April 15, 2011 **Federal Register**, we published a final rule entitled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' (''April 15, 2011 final rule''), which governs the dispensing of prescription drugs in LTC facilities under Part D plans. In accordance with § 423.154, Part D sponsors generally must require their network pharmacies to dispense certain solid oral brand covered Part D drugs in quantities of 14 days or less, unless an exemption applies. As a clarification to the April 15, 2011 final rule, we proposed in the January 2014 proposed rule the following specific changes to the LTC short cycle dispensing requirements:

- Add a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed, and a requirement to ensure that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques.
- Eliminate language that has been misinterpreted as requiring the proration of dispensing fees.
- Incorporate an additional waiver for LTC pharmacies using restock and reuse dispensing methodologies under certain conditions.
- Make a technical change to eliminate the requirement that Part D sponsors report on the nature and quantity of unused brand and generic drugs.

After providing a summary of the current LTC short cycle dispensing rule in the proposed rule, we addressed each proposed change in more detail.

a. Prohibition on Payment Arrangements That Penalize the Offering and Adoption of More Efficient LTC Dispensing Techniques (§ 423.154)

Our first proposed change was to add a paragraph to § 423.154 prohibiting payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed, and a requirement to ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques. Certain dispensing fee payment arrangements, for example, some proration arrangements, penalize the offering and adoption of more efficient LTC dispensing. For instance, if a medication is discontinued before a month's supply has been dispensed, a pharmacy that dispenses the maximum amount of the medication at a time permitted under § 423.154 (for example, 14 days), collects more in dispensing fees than a pharmacy that utilizes dispensing techniques that result in less than maximum quantities being dispensed at a time. In other words, the least efficient pharmacy collects more in dispensing fees than a more efficient pharmacy.

In the proposed rule, we provided the following example of two pharmacies—one more efficient at dispensing than the other—to illustrate our concern: A monthly $4.00 dispensing fee for a 30-days' supply is prorated, and a medication is discontinued after 21 days. The first pharmacy dispenses 14-days' supply at a time and receives approximately $3.73 in total dispensing fees for a 28-days' supply ($0.1333 × 28), which results in 7 days' worth of medication waste. The second pharmacy dispenses 3-days' supply at a time and receives approximately $2.80 in dispensing fees for a 21-days' supply in total ($0.1333 × 21), which results in no medication waste.

We believe this example is contrary to the Congress' intent in enacting section 3310 of the Affordable Care Act, which was to reduce medication waste. In this example, the second pharmacy's more efficient dispensing techniques results in less medication waste, but the pharmacy itself receives less in dispensing fees than it would if it had dispensed in 14-day increments, which result in more medication waste. This approach creates a perverse incentive for LTC pharmacies to adopt the least efficient dispensing technique, if available, which is to dispense drugs in 14 days supplies. This encourages wasteful dispensing to the Part D program.

Given the clear intent of the Affordable Care Act to reduce wasteful dispensing in the LTC setting, we proposed to prohibit payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by adding a new requirement that would state a Part D sponsor must not, or must require its intermediary contracting organizations not to, penalize long term care facilities' choice of more efficient uniform dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. We proposed that this requirement would also state that a sponsor or its intermediary contracting organizations must ensure that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques.

b. Misinterpretation of Language as Requiring the Proration of Dispensing Fees (§ 423.154)

Our second proposed change to § 423.154 was to eliminate paragraph (e), which we believe has caused confusion. Section 423.154(e) currently states that regardless of the number of incremental dispensing events, the total cost sharing for a Part D drug to which the dispensing requirements under this paragraph (a) apply must be no greater than the total cost sharing that would be imposed for such Part D drug if the requirements under paragraph (a) of this section did not apply. The purpose of this language was to ensure that sponsors did not assess multiple monthly copayments for each incremental dispensing event in LTCs. We believe misinterpretation of paragraph (e) may have prompted some sponsors to prorate dispensing fees in a way that penalizes the offering and adoption of more efficient LTC dispensing techniques, even though the current regulation does not address dispensing fees.

Moreover, effective January 1, 2014, the daily cost-sharing rate requirement in § 423.153(b)(4)(i) applies whenever a prescription is dispensed by a network pharmacy for less than a month's supply, unless the drug is excepted, regardless of the setting in which the drug is dispensed. In other words, the daily cost-sharing rate requirement applies to brand drugs dispensed in LTC facilities to the extent they must be dispensed in supplies less than 30 days under § 423.154, and to generic drugs, to the extent a sponsor voluntarily dispenses generic drugs in LTC facilities in supplies less than a month's supply. Consequently, the requirement of § 423.153(b)(4)(i) makes § 423.154(e) unnecessary, and we believe retaining both provisions could cause further confusion. For these reasons, we proposed to delete § 423.154(e).

c. Additional Waiver for LTC Pharmacies Using Restock and Reuse Dispensing Methodologies Under Certain Conditions (§ 423.154)

Our third proposed change to § 423.154 was to waive the short-cycle dispensing requirements for LTC pharmacies meeting certain conditions. Currently, § 423.154(c) waives the requirements for pharmacies when they dispense brand name Part D drugs to enrollees residing in intermediate care facilities for the mentally retarded and institutes for mental disease, as well as for I/T/U pharmacies. We have learned that some institutional pharmacies maintain custody of medications within the LTC facilities through operating a closed pharmacy within the facility, and as a result can ensure sufficient quality control over these medications to return all unused medications to stock for reuse that are eligible for return and reuse under applicable law. This has led us to believe there is another category of pharmacies, such as some on site pharmacies in veterans' homes, for which a waiver from the LTC short-cycle dispensing requirement may be appropriate, if they meet certain conditions that demonstrate that applying the 14-day dispensing requirements in these instances would not serve to reduce waste.

In light of this, we proposed to waive the requirements of § 423.154(a) for an LTC pharmacy that exclusively uses the dispensing technique of returning all unused medications to stock that can be restocked under applicable law for reuse and rebating full credit for the ingredient costs of the unused medication to the PDP sponsor. The proposed waiver also would require that for those drugs that cannot be returned for full credit and reuse under applicable law, such as controlled substances, the pharmacy uses a dispensing methodology that results in the delivery of no more than 14 days of a drug at a time. We proposed that the waiver would apply on a uniform basis to all similarly situated LTC pharmacies, but not to a pharmacy organization that is contracted to use this technique at some, but not all, of its pharmacies. Rather, the waiver would apply only to the qualifying pharmacies themselves. We proposed that we would not require the pharmacies to credit back any amount of the dispensing fee when the pharmacies return a drug to stock for reuse, since the level of effort for the pharmacies would not be expected to decrease. We stated that, if anything, the level of effort would be increased, since the pharmacies have to implement the appropriate internal controls for inspection and return to inventory of the unused medication.

We further solicited comments on our proposal that to qualify for the waiver, a pharmacy would have to dispense any drugs that cannot be restocked under applicable law, such as controlled substances, in no greater than 14-day supply increments. Our rationale in proposing this condition to the waiver is that we do not want the waiver to inadvertently result in large quantities of medications being dispensed to Part D enrollees serviced by the pharmacies that would qualify for the waiver because they cannot be restocked under applicable law.

d. Technical Change To Eliminate the Requirement That PDP Sponsors Report on the Nature and Quantity of Unused Brand and Generic Drugs (§ 423.154)

Finally, we proposed to make a technical change to § 423.154(a)(2), which requires Part D sponsors to collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section, as well as on the nature and quantity of unused brand and generic drugs dispensed by the pharmacy to enrollees residing in an LTC facility. This latter reporting requirement is waived for sponsors for drugs dispensed by pharmacies that dispense both brand and generic drugs in no greater than 7-day increments.

In a memorandum titled, ''Modifications to the Drug Data Processing System (DDPS) in Relation to Appropriate Dispensing of Prescription Drugs in Long Term Care Facilities,'' issued by CMS on August 3, 2012, we explained that we planned to use the PDE data in conjunction with other CMS data (such as MDS) to determine the extent to which 14 day or less dispensing to enrollees in LTC facilities reduces the amount of unused drugs in LTC. We did this to lessen the burden on sponsors that would be created by a separate reporting requirement. Therefore, it is no longer necessary to waive the reporting requirement for any Part D sponsor, because Part D sponsors comply with the requirement (in the form and manner we specified in the previously-referenced memorandum) via PDE submission. Thus, we proposed deleting the language in in § 423.154(a)(2) that appeared to require separate reporting, to eliminate any confusion.

We received the following comments on this proposal and our responses follow:

Comment: Numerous commenters support the proposal to add a prohibition on payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed, and a requirement to ensure that any difference in payment methodology among long term care pharmacies incentivizes more efficient dispensing. Many of these comments in particular supported CMS' view that there is not a justifiable reason for proration of monthly dispensing fees since the cost of dispensing is not directly related to the quantity dispensed. These commenters asserted that proration of dispensing fees ignored

the clinical oversight and fixed costs for pharmacy professional services for each dispense. These commenters acknowledged that prorated professional fees have resulted in a perverse economic model that encourages pharmacies to dispense the maximum allowable quantity of drugs (for example, 14 days supplies) in each prescription drug event transaction.

Other commenters opposed this proposal, stating that it would increase costs by requiring a full dispensing fee with each dispensing event in an LTC facility, and that since the LTC pharmacies determine dispensing increments, this will incentivize them to select the system that provides the highest number of dispensing fees. These commenters also noted that the Affordable Care Act did not specify a new LTC dispensing fee structure.

A commenter provided an illustrative example of prorated monthly dispensing fees that may not penalize the offering and adoption of more efficient LTC dispensing techniques. Specifically, the example demonstrates how an increased dispensing fee with proration can create appropriate incentives to reduce waste and cost in LTC facilities. The example provided for a $10 base dispensing fee for a 30-day supply for a pharmacy with technology that dispenses in 7-day increments and a $4.00 base dispensing fee for a pharmacy that dispenses in 14-day increments. Under this scenario, the more efficient pharmacy would receive $2.31 for dispensing 7 days of medication ($10/30 = $0.33 × 7) and the less efficient pharmacy would receive $1.82 ($4/30 = $0.13 × 14) for dispensing 14 days of medication. This commenter urged us to allow for any dispensing structure where the daily dispensing fee encourages all pharmacies, regardless of their size or negotiation capabilities, to use the most efficient dispensing technologies.

Response: We thank the supportive commenters for their comments. With respect to the commenters that opposed the proposal, we note that the proposal did not require a full monthly dispensing fee with each dispensing event, or any specific dispensing fee or methodology for that matter. The intent of this rule is to prohibit dispensing fees that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. This rule also adds a requirement to ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.

With respect to the one commenter that pointed out that certain prorated dispensing fees may not penalize the offering and adoption of more efficient LTC dispensing techniques in certain instances, we take no position at this time on whether specific dispensing fee arrangements would be compliant with this rule. We reiterate that this rule does not require a specific dispensing fee or methodology, but rather, prohibits payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. In addition, this rule requires that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques.

Comment: A commenter stated that because its data shows 80 percent of all LTC dispense claims are for generic medications, modifying dispensing fees will not truly affect the use of short-cycle methodology. This commenter requested that CMS provide any research demonstrating the increased utilization of short-cycle fill in dispensing in pharmacies whose dispensing fees did not change to a prorated fee. Alternatively, this commenter requested CMS' observations and supporting data demonstrating that a daily dispensing fee actively discourages pharmacies from short-cycle filling medications.

Response: We do not believe the research and data requested are necessary to finalizing this proposal. We believe it is self-evident that proration of the same monthly dispensing fee based on days' supply or quantity dispensed (which results in a type of daily dispensing fee or rate) penalizes more efficient pharmacies relative to less efficient ones—the more efficient pharmacy is reimbursed less per dispense because it dispenses in smaller increments. Moreover, that prorated dispensing fee decreases per dispense the more efficiently the pharmacy dispenses.

Comment: A commenter stated that CMS confuses prorated dispensing fees with daily dispensing fees that are not necessarily pro rata adjustments of otherwise applicable dispensing fees.

Response: Our prohibition of proration that penalizes more efficient dispensing would apply both to proration of a monthly dispensing fee amount and proration determined by setting a daily rate that is applied to the number of days dispensed. The intent is of our rule is to prohibit payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed, and to require that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques.

Comment: A commenter stated that PBMs have very little leverage in negotiating cost effective strategies with LTC pharmacies on behalf of Part D sponsors, as the LTC landscape is controlled by three very large LTC pharmacy organizations that make up an estimated 80 percent of the market share, and that in many cases, only one of them is the provider of prescription medications in LTC facilities. This commenter further stated that these LTC pharmacy organizations dictated the contractual requirement to prorate dispensing fees, asserting that their member LTC pharmacies needed compensation for every prescription fill.

Response: This rule prohibits payment arrangements that penalize the offering and adoption of more efficient LTC dispensing techniques by prorating dispensing fees based on days' supply or quantity dispensed. For example, this rule prohibits payment arrangements that penalize LTC dispensing techniques of less than 14 days supplies of drugs at a time. This rule also requires that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques. For example, this rule requires that differences in payment methodologies among LTC pharmacies incentivize dispensing techniques of less than 14 days supplies of drugs at a time. If the prorated dispensing fees by days' supply or quantity dispensed do not penalize the offering of more efficient dispensing techniques by these LTC pharmacies, and any difference in payment methodology relative to other LTC pharmacies incentivizes more efficient dispensing techniques, then this regulatory provision is not implicated.

Comment: Some commenters asserted that our proposal was a violation of the non-interference clause and exceeded our delegated authority.

Response: We disagree. Section 1860D–4(c)(3) of the Act provides that the Secretary shall require Medicare Part D sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, such as weekly, daily, or automated dose dispensing, when dispensing covered Part D drugs to enrollees who reside in a LTC facility in order to reduce waste associated with 30-day fills. Thus, the Congress gave the Secretary authority to regulate with respect to reducing waste of covered Part D drugs in LTC facilities. Moreover,

this requirement does not dictate any specific dispensing fee amounts or methodologies, but rather prohibits only those dispensing fees that penalize more efficient dispensing and requires that any difference in payment methodology among LTC pharmacies incentivizes more efficient dispensing techniques. For the reasons stated previously, we believe this is consistent with the statutory directive to reduce waste associated with 30-day fills in LTC facilities.

Comment: A commenter stated the regulatory text was vague.

Response: We disagree. The policy reflected in the preamble and regulatory text is clear—to prohibit the prorated LTC dispensing fees in the Part D market today that are financially penalizing more efficient LTC pharmacies. In addition, we believe the discussion in this preamble, with examples provided, makes clear how sponsors must not penalize more efficient dispensing techniques in LTC facilities by prorating dispensing fees based on days' supply or quantity dispensed and that any difference in payment methodologies among LTC pharmacies must incentivize more efficient dispensing techniques. We have deliberately struck a balance in drafting the regulatory text to be specific enough to accomplish the policy goal without being so specific as to dictate the particular dispensing fee arrangements that are permissible.

Comment: A commenter requested whether this new requirement applies to all payments to LTC pharmacies; whether it applies to all prescriptions in LTC facilities or only to those subject to the short-cycle dispensing methodology; and whether a Part D sponsor must prove to each LTC pharmacy how its payment methodology incentivizes more efficient dispensing techniques.

Response: The requirement in this final rule applies to payments to pharmacies related to the dispensing of Part D drugs to residents in LTC facilities, including those Part D drugs that are not subject to the short-cycle dispensing requirement. As noted previously, this rule does not address specific negotiations between Part D sponsors and pharmacies.

Comment: One commenter stated that the regulatory text was confusing and contained three negatives.

Response: We are moving the proposed language to § 423.154(a)(2) and (3) and revising the regulation text. We believe this will make the regulatory text less confusing. However, because we did not propose to waive this requirement with respect to pharmacies when they dispense Part D drugs to residents of intermediate care facilities for the mentally retarded (ICFs/IID) and institutes for mental disease (IMDs) and for I/T/U pharmacies, we are making conforming changes to § 423.154(c) to make clear that the requirements of paragraph (a)(2) and (3) are not waived for with respect to these pharmacies.

Comment: A commenter stated that it was unnecessary for CMS to memorialize the fact that the rule applies to contracting intermediaries in addition to Part D sponsors in the regulatory text.

Response: We agree. The reference to ''intermediary contracting organizations'' in the regulatory text is now unnecessary because we are moving the requirement to § 423.154(a)(2) and (3), as noted just previously.

Based on all the comments received, we are finalizing our proposal with the changes previously described in this section.

Comment: Some commenters supported the removal of the language in § 423,154(e) that CMS believes may have been misinterpreted as requiring the proration of dispensing fee. A few commenters opposed this proposal. One of these commenters that opposed this proposal stated that plans did not interpret the provision as requiring the proration of dispensing fees, but rather as permitting it.

Response: Based on the comments received, we are finalizing the removal of this language from the current regulatory text. As noted previously, this provision was intended to address cost sharing for short-cycle dispensing in LTC facilities, but the daily cost-sharing rate rule at § 423.153(b)(iv)(i) now addresses cost-sharing when less than a month's supply of a Part D drug is dispensed. Thus, this regulatory text is no longer necessary. Moreover, we believe the comments support our view that the language was confusing.

Comment: Several commenters supported CMS' proposal in principle for an additional waiver from the short-cycle dispensing requirements for certain LTC pharmacies that maintain custody of medications by operating a closed pharmacy within the facility, but these commenters expressed concerns about how the waiver would be implemented. Specifically, these commenters pointed out that there is no current transaction standard that accommodates transmitting a net quantity for payment following the acceptance of a returned medication applied against a quantity dispensed for ingredient cost credit, and that use of an existing transaction to accomplish this would violate HIPAA. These commenters stated that a new HIPAA standard transaction would be required to support a waiver based on return and reuse billing.

Response: In the proposed regulation, while we used an industry term of art ''restock and reuse,'' we did not intend to implicate a billing standard that does not exist. This term, as used in the industry, encompasses a billing system that modifies pharmacy claims as unused medications are returned to stock. We are aware of the current limitations of this particular system.

The type of pharmacy that would qualify for the waiver, as we described in the proposed rule, is an institutional, on-site, closed pharmacy, such as a pharmacy in a veteran's home, which maintains custody of medications within the LTC facility, such that all unused medications that are eligible under applicable law are restocked and reused. In other words, such a pharmacy has such quality control over medications in the LTC facility that it does not have to dispense in 14-day supplies or less in order to reduce waste. Such pharmacies may use post-consumption billing, a reverse and rebill system, or some other billing method to only charge a Part D sponsor for the medications that are actually used.

Given the misunderstanding of our proposed additional waiver from the LTC short-cycle dispensing rule, we are not finalizing it as this time. We will consider proposing the waiver again in future rulemaking.

Comment: We received no comment on our proposal to delete language in § 423.154(a)(2) to eliminate any confusion about that there is a separate reporting requirement.

Response: We are finalizing this deletion, except that we are redesignating the remaining language in (a)(2) as (a)(4) in light of the other changes previously described.

Comment: Some commenters requested a delay in the effective date of this requirement until 2016, asserting that the requirement will necessitate significant changes in adjudication and network contracting logic to accommodate the replacement of prorated dispensing fees with standard dispensing fees. One commenter requested clarification of the effective date of this requirement.

Response: The effective date of this requirement is January 1, 2016.

6. Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325)

Section 3301 of the Affordable Care Act, codified in section 1860D–43 and 1860D–14A of the Act, established the

Medicare Coverage Gap Discount Program (Discount Program), beginning in 2011. Under the Discount Program, manufacturer discounts are made available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap. Section 1860D–14A(c)(1)(A)(ii) of the Act requires the manufacturer discount to be provided to beneficiaries at the point-of-sale. Employer Group Waiver Plans (EGWPs) are customized employer-offered plans available exclusively to employer/union health plan Part D eligible retirees and/or their Part D eligible spouse and dependents. Section 423.458(c)(4) requires sponsors offering EGWPs to comply with all Part D requirements unless those requirements have been specifically waived or modified by CMS using our authority under section 1860D–22(b) of the Act. The Affordable Care Act did not exclude EGWP enrollees that otherwise meet the definition of an applicable beneficiary (as defined in § 423.100) from the Discount Program. Therefore, in order for an applicable drug to be covered by EGWPs, it must be covered under a manufacturer agreement, and the manufacturer must pay applicable discounts for applicable beneficiaries as invoiced.

Beginning in 2014, all EGWP benefits beyond the parameters of the defined standard benefit will be treated as non-Medicare Other Health Insurance (OHI) that wraps around Part D. We excluded supplemental coverage offered through EGWPs from the definition of Part D supplemental benefits in § 423.100 in our 2012 rulemaking. However, as discussed in section II.E.14. of this final rule, the change was erroneously not included in the CFR. Therefore, we are making a technical change to rectify that problem. The change with respect to EGWPs was made so that the discount amount could be consistently and reliably determined. This was necessary to ensure that we can determine that the discount is always calculated accurately since we do not collect information on all EGWP retiree benefit arrangements to determine actual supplemental benefits. Not only would collecting such information be impractical, but we also believe instituting a requirement to collect the specific information on all such benefits would be so burdensome as to hinder the design of, the offering of, or the enrollment in employer plans. Consequently, the discount calculation is based upon the Part D Defined Standard benefit for all EGWPs beginning in 2014. While we believed that our justification for excluding any supplemental benefits offered through EGWPs from Part D benefits clearly indicated that the basic EGWP Part D benefits would be limited to Defined Standard benefit because that is the only way we can determine that the discount is calculated accurately, we took the opportunity to propose this specific requirement in § 423.2325(h)(1) to remove any ambiguity.

Comment: Some commenters strongly urged CMS to revise the policy established in our April 2012 rule that considers EGWP plan supplemental benefits to be outside of Part D, and therefore OHI. These commenters stated that treating EGWP benefits as OHI is inconsistent with the statute as it does not, on its face appear to result in direct reductions in beneficiary cost sharing. They state that since many EGWP enrollees do not experience a coverage gap the discounts are not used to offset beneficiary spending in the gap which is the original statutory intent. A few commenters stated that the current policy has led employer groups to migrate from Retiree Drug Subsidy plans to EGWPs which is costly to the taxpayer.

Response: We did not propose any changes to our existing policy with respect to EGWP supplemental benefits, and we decline to do so now. For the reasons set forth in our April 2012 rulemaking, we believe our current regulation is consistent with the statute. The purpose of this final rule is solely to clarify that basic EGWP benefits are to be based upon the Defined Standard benefit.

After considering the comments received, we are finalizing the portion of the provision which proposed that Part D sponsors offering employer group waiver plans must provide applicable discounts to EGWP plans as determined consistent with the Defined Standard benefit, except we are making a technical change to clarify that applicable discounts are available only to applicable beneficiaries enrolled in the EGWPs. We are not finalizing the proposed requirement that Part D sponsors of EGWPs disclose to each employer group the projected and actual manufacturer discount payments under the Discount Program attributable to the employer group's enrollees, at least annually or upon request.

7. Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes During the Coverage Year (§ 423.464)

Sections 1860D–23 and 1860D–24 of the Act specify that requirements for Part D sponsor coordination of benefits with State Pharmaceutical Assistance Programs and other plans providing prescription drug coverage, including treatment of expenses incurred by these payers toward a beneficiary's out-of-pocket (TrOOP) threshold. Part D coordination of benefit requirements are codified at § 423.464, which defines ''other prescription drug coverage'' for COB purposes to include, among other entities, other Part D plans, and specifies Part D plan requirements for determining when an enrollee has satisfied the out-of-pocket threshold.

Related regulations at § 423.104(d), codifying the requirements in section 1860D–2(b) of the Act, require sponsors to track beneficiary TrOOP and gross covered drug costs and correctly apply these costs to the benefit limits to correctly position the beneficiary in the benefit and provide the catastrophic level of coverage at the appropriate time. When a beneficiary transfers enrollment between Part D plans during the coverage year, the enrollee's gross covered drug costs and TrOOP must be transferred between plans and applied by the subsequent plan in its administration of the Part D benefit. The process for a prior plan to report these TrOOP-related data and for the new plan of record to receive, upload, and use the data position the beneficiary in the correct phase of the benefit was initially manual.

In 2009, this process was replaced by an automated process for TrOOP-related data transfer. Our guidance released in 2008 (HPMS memorandum dated October 21, 2008 titled, ''Updated Part D Sponsor Automated TrOOP Balance Transfer Operational Guidance'') described sponsor implementation of the automated TrOOP balance transfer process and reiterated sponsor requirements for data reporting by the prior plan and use of the data for proper positioning of the beneficiary in the benefit by the current plan. We have continued to specify these requirements in subsequent updated versions of the guidance.

To ensure Part D benefits are correctly administered when a beneficiary transfers enrollment during the coverage year, we proposed to codify these requirements in federal regulations. Specifically, we proposed to amend § 423.464(f)(2) by adding a new paragraph (C) requiring Part D sponsors to—

- Report benefit accumulator data in real time in accordance with the procedures established by CMS;
- Accept in real-time data reported in accordance with CMS-established procedures by any prior plans in which the beneficiary was enrolled, or that paid claims on the beneficiary's behalf, during the coverage year; and

• Apply these costs promptly.

In our guidance on automated TrOOP balance transfer, we express our expectation that sponsors successfully transfer accumulator data for beneficiaries making enrollment changes during the coverage year in a timely manner 100 percent of the time. Although sponsors may be reporting and accepting these data in accordance with our expectations, we have been informed that some sponsors may not be promptly loading the data received into their systems so it is available for claims processing. As a result, the beneficiary's previously incurred costs and gross covered drug costs are not considered in the processing of claims received by the new plan sponsor soon after the enrollment change.

Comment: One commenter objected to the provision claiming it was vague and ill-defined and requested we include additional detail in lieu of deferring to sub-regulatory guidance.

Response: We disagree. The proposed regulatory text specifies the requirements for sponsors to report, accept and apply accumulator data. We believe the details of the transfer process are more appropriately addressed in guidance because they are procedural, and retaining them in guidance will preserve flexibility to adapt these procedures as the need arises. CMS and the industry developed the automated data transfer process in collaboration with National Council for Prescription Drug Programs (NCPDP) and have continued to work collaboratively to refine and improve the process. When a change in the transfer process is agreed upon and substantive requirements are unaffected, use of guidance permits us to issue updated instructions in a timely manner.

Comment: Three commenters expressed support for the provision.

Response: We appreciate the support for this provision and are adopting this provision as proposed with a minor change. That is, we are redesignating the current paragraph (B) in § 423.464(f)(2)(i)(B) as (C) and adding this provision as paragraph (B) to more logically sequence the requirements.

8. Expand Quality Improvement Program Regulations (§ 422.152)

Section 1852(e) of the Act requires MA organizations to have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees.

We proposed revising paragraph (a) of § 422.152 in order to codify our recent expansion of the quality improvement program policies and revising paragraph (c) of § 422.152 to codify our recently expanded chronic care improvement program policies. The proposed revisions to these paragraphs more accurately reflect current quality care improvement program policies and requirements.

Additionally, paragraph (g) of § 422.152 lists quality improvement program requirements that are specific to special needs plans (SNPs). We proposed revising paragraph (g) to clarify that the requirements listed there are in addition to program requirements listed in paragraphs (a) and (f) of § 422.152 and are not instead of the regular quality improvement program requirements.

Finally, we proposed to delete paragraph (h)(2) of § 422.152 as it pertains to contract year 2010 and is no longer relevant.

We received the following comments and our responses are as follows:

Comment: We received several comments that supported § 422.152 overall and CMS efforts to implement policies that ensure high quality health care for enrollees.

Response: We thank the commenters for their support.

Comment: One commenter requested clarification as to what exactly has changed under § 422.152(c), ''Chronic care improvement program requirements,'' as it appears to expand only one requirement and reorder the others.

Response: Our proposal, and the finalized rule here, revises paragraphs (c)(1)(ii) to add a requirement for the MA organization to evaluate participant outcomes (such as changes in health status), and add paragraphs (c)(1)(iii), (c)(1)(iv), and (c)(2). Paragraph (c)(1)(iii) requires performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research, and (c)(1)(iv) requires systematic and ongoing follow-up on the effects of the chronic care improvement program. Finally, new paragraph (c)(2) requires that the organization report to CMS on the results of each chronic care program. The proposed changes also included reorganization of the section to parallel requirements in paragraph (d), ''Quality improvement projects.''

Comment: One commenter requested whether recent changes to the SNP Model of Care (MOC) requirements would be the vehicle for evaluating compliance in relation to the effectiveness of a plan's Model of Care.

Response: This comment is outside the scope of the proposed changes to this provision because we did not propose, and are not finalizing in this rule, any changes to the SNP MOC requirements. Information about the MOC and associated requirements can be found in Chapter 5 of the Medicare Managed Care Manual.

Comment: One commenter requested clarification on the additional quality improvement program requirements for SNP plans.

Comment: The changes made to this provision do not create any new quality improvement program requirements for SNPs. The changes are to clarify the requirement that SNPs must comply with the requirements under paragraph (g) as well as those in paragraphs (a) through (f). The SNP-specific requirements in paragraph (g) do not replace the requirements in paragraphs (a) through (f), which apply to all plans, including SNPs.

Comment: A commenter requested whether Quality Improvement Project and Chronic Care Improvement Program results will be included in Star Rating measurements in the near future.

Response: This comment is outside the scope of the proposed changes to this provision as we did not propose, and are not finalizing in this rule, any Star Rating measures in connection with the quality improvement program requirement.

Comment: A commenter expressed opposition to expanded quality improvement requirements as a whole because MA organizations respond to such requirements by setting unrealistic targets for physicians. The commenter added that compliance must often be at 100 percent for a physician to qualify for a payment incentive.

Response: Our proposal codifies our recent expansion of the quality improvement program policies and revises paragraph (c) of § 422.152 to codify our recently expanded chronic care improvement program policies. The proposed revisions to these paragraphs more accurately reflect current quality care improvement program policies and requirements that are already in practice. While we understand the commenter's concern, we do not agree that codifying requirements that are already in practice will place any further burden on MA organizations and thus tangentially increase the burden on physicians. Additionally, while we understand that our recent expansion of our quality improvement program policies may have impacted MA organizations and, in turn, providers, the requirements do not specify any provider requirements or address payment incentives of any type. MA organizations and providers remain free to contract and make agreements on

these topics without CMS interference, thus MA organizations have flexibility when shaping their provider processes, policies, and overall framework.

Comment: A commenter stated that CMS's guidance with respect to Quality Improvement Projects and Chronic Care Improvement Programs for SNP plans has been unclear.

Response: Our proposal, and this final rule, revises paragraph (g) to clarify that the requirements listed there are in addition to program requirements listed in paragraphs (a) and (f) of § 422.152 and are not in lieu of the quality improvement program requirements presented in paragraphs (a) and (f). We believe the revisions to the regulation clarify that Quality Improvement Project and Chronic Care Improvement Program requirements are the same for SNP and non-SNP plans.

After consideration of the public comments received, we are finalizing the proposed codification and clarification of our Quality Improvement Program regulation at § 422.152 without modification.

B. Improving Payment Accuracy

1. Determination of Payments (§ 423.329)

In the January 2014 proposed rule, we proposed a technical change to § 423.329(d) to correctly describe the low-income cost-sharing subsidy payment amount as it is intended by statute and has been implemented and described in interpretive guidance by CMS. That amount had been defined in the regulation as the amount described in § 423.782. However, § 423.782 refers to the cost sharing paid by the beneficiary, not the cost-sharing subsidy paid on behalf of the low-income subsidy-eligible individual. The low-income cost-sharing subsidy amount is correctly described in Chapter 13 of our Medicare Prescription Drug Benefit Manual, Premium and Cost Sharing Subsidies for Low Income Individuals ((Rev. 13, 07–29–11), at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/Chapter13.pdf*). As we stated in the proposed rule, under the basic benefit defined at § 423.100, the low-income cost-sharing subsidy payment amount is the difference between the Part D cost sharing for a non-LIS beneficiary under the Part D plan and the statutory cost-sharing for the LIS-eligible beneficiary. Under an enhanced alternative plan described at § 423.104(f), the cost-sharing subsidy applies to the beneficiary liability after the plan's supplemental benefit is applied. We proposed to amend § 423.329(d) consistent with this guidance.

We also explained in our proposed rule that pursuant to § 423.2305, any coverage or financial assistance other than basic prescription drug coverage, as defined in § 423.100, offered by an employer group health or waiver plan is considered ''other health or prescription drug coverage.'' This definition applied to all of Medicare Part D. (See the April 12, 2012 final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' (77 FR 22082)). Therefore, the subsidy amount received by an employer group health or waiver plan is the subsidy amount received by a Part D plan offering defined standard coverage, as defined in § 423.100.

Based on the preceding, we proposed to amend § 423.329(d) by deleting the reference to §§ 423.782 and amending 423.329(d) to define the low-income cost-sharing subsidy payment amount on behalf of a low-income subsidy-eligible individual enrolled in a Part D plan for a coverage year as the difference between the cost sharing for a non low-income subsidy eligible beneficiary under the Part D plan and the statutory cost sharing for a low-income subsidy-eligible beneficiary.

In order to clarify that enhanced alternative benefits apply prior to determining the low-income cost-sharing subsidy payment amount, we clarify in this preamble and in the final regulation text that the low-income cost-sharing subsidy payment amount is the difference between the cost sharing (not the ''Part D cost sharing,'' as proposed) for a non-LIS beneficiary under the Part D plan and the statutory cost sharing for the LIS-eligible beneficiary.

We received no comments on this proposal and are finalizing with a minor modification, as discussed previously.

2. Reopening (§ 423.346)

We proposed to amend the reopening provisions such that we may perform one reopening within 5 years after the date of the notice of the initial payment determination to the Part D sponsors. We also proposed to amend the provision to accommodate reopening the Coverage Gap Discount Reconciliation described at § 423.2320(b).

As we stated in the proposed rule, we had originally patterned the reopening provisions after the Medicare claims reopening regulations found in part 405, but now with a better understanding of the need for reopening a payment determination, we proposed to modify our regulation at § 423.346 to align with our experience. We stated that our experience indicates to us that we will likely have to perform a reopening of the initial payment determination for every contract year, and we proposed to remove the current timeframes for a reopening described in § 423.346(a)(1) through (a)(3), remove paragraph (b) describing ''good cause'' referred to in paragraph (a)(2), modify paragraph (c) to eliminate the reference to ''good cause,'' and amend paragraph (a) such that CMS may reopen one time within 5-years of notice of the initial payment determination.

As stated in the proposed rule, we believe that data stability will occur within 5 years of the notice of the initial payment determination. Within 5-years of the notice of the initial payment determination, additional prescription drug event (PDE) data or PDE adjustments associated with coordination of benefits will be submitted by Part D sponsors consistent with the timeframe described at § 423.466(b). We know that audits and other post reconciliation oversight activity often take place more than 5-years from notice of the initial payment determination. However, in light of the overpayment provision at section 6402(a) of the Affordable Care Act, which established section 1128J(d) of the Act and that we proposed to codify at § 423.360, we stated that we do not believe that it is necessary to reopen a payment reconciliation after that 5-year period, and that we believe it is not necessary to reopen a reconsidered payment determination. Therefore, we proposed to amend § 423.346(a) such that we will only reopen the initial payment determination and will not reopen a reconsidered payment determination.

With respect to determining whether to reopen a contract year, we stated that we will consider a number of issues, including, but not limited to, whether the contract has terminated and received a final settlement. We stated that we will not approve a request to reopen for a contract that has terminated and received a final settlement. We also stated that when we performed a reopening on our own initiative, contracts that have been terminated and settled will not be included in the reopening.

In addition, we proposed to establish a reopening provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that we established a reopening provision for the Part D payment reconciliation process described in our January 28, 2005 final

rule titled, ''Medicare Program; Medicare Prescription Drug Benefit'' (70 FR 4316). We noted that in a Health Plan Management System (HPMS) memorandum dated April 30, 2010, we stated that the final reconciled discount program payments are subject to the reopening provision in § 423.346. Due to the invoicing process that continues to occur after the reconciliation process, we do not anticipate the need to reopen the Coverage Gap Discount Reconciliation. However, we want to leave open the option to reopen if unforeseen events result in underpayments or overpayments to Part D sponsors. Therefore, we proposed to amend § 423.346 to accommodate reopening a Coverage Gap Discount Reconciliation.

Based on the preceding, we proposed to revise § 423.346 by removing the phrase ''or reconsidered'' from paragraph (a), amending paragraph (a) to account for the proposed timing of the Part D reopening, removing paragraphs (a)(1) through (3) and (b)(1) through (3); adding a new paragraph (b) to accommodate a Coverage Gap Discount Reconciliation reopening; and revising paragraph (c) to eliminate the reference to ''good cause.''

We received the following comments and our responses follow:

Comment: A commenter stated that the past 6 years indicate that unforeseen issues arise and require multiple reopenings to address them properly. A commenter recommended that CMS relax the proposed regulation and not unnecessarily restrict CMS's ability to conduct more than one reopening. A commenter supported the goal of one reopening per contract year, but recommended that CMS set a threshold, such as a dollar amount, to restrict reopenings while preserving an appropriate amount of flexibility in the regulation to accommodate circumstances with a degree of materiality.

Response: We agree with the commenter that multiple reopenings may be necessary. We know from experience that there are unforeseen circumstances that require us to do multiple global or targeted reopenings for a contract year. Target reopenings include reopening for a specific plan type (for example, PACE organizations) or for specific contracts or parent organizations. For this reason and also due to potential conflicts between the 5-year time frame of this proposed provision and the 6-year look-back period associated with the overpayment provision recently codified at § 423.360 (see 79 FR 29847), we are not finalizing the proposal to reopen one time within 5 years after the date of the notice of the initial determination to the Part D sponsors.

Our proposal to do one reopening within 5 years after the date of the notice of the initial determination may create difficulties for Part D sponsors to return overpayments that they identify and are required to report and return under § 423.360. Section 423.360 creates a 6-year look-back period at § 423.360(f). In accordance with § 423.360(f), a Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years. In our May 23, 2014 final rule, (79 FR 29843), we stated that CMS would recover plan-identified overpayment amounts through routine processing. For Part D, that means that if an overpayment is discovered, the Part D sponsor may fulfill its obligation to return the overpayment by requesting a reopening and submitting corrected data prior to CMS conducting the reopening. (For more information, see 79 FR 29923). To the extent possible, we want to allow for overpayments to be recovered through routine payment processes through the entire 6-year look-back period. The decision not to finalize our proposal to conduct one reopening within a 5-year period gives the Part D sponsor more flexibility to return overpayments and CMS more flexibility to collect overpayments through routine payment processes. Therefore, we are not finalizing the proposed provision that CMS will reopen one time within 5 years after the date of the notice of the initial determination to the Part D sponsors.

We note that we agree with the commenter that making the decision whether to reopen could be based on a dollar amount threshold. We currently consider several factors, including dollar amount, to determine whether to do a reopening. However, the decision of whether or not to do a reopening beyond the initial global reopening will be decided based on factors specific to the circumstance. For that reason, we will not codify a threshold or any other list of factors that would give rise to multiple reopenings.

Comment: A few commenters disagreed with our approach to do one global reopening. A commenter stated that unfocused reopenings would place a great burden on Part D sponsors, particularly when looking back as much as 5 years, and recommended that the current rule, requiring ''good cause'' for a reopening after 1 year after the final payment determination, remain in place. A commenter also considered the possibility of extending the timeframe beyond the current 4 years to 5 years for reopening with cause.

Response: Although we are not finalizing the proposed provision that we will reopen one time within 5 years after the date of the notice of the initial determination to the Part D sponsors, we disagree with the commenter's statement that unfocused reopenings will place a great burden on Part D sponsors. We conduct reopenings after we see stability in the PDE and DIR data. We track the number of PDEs that we receive for each contract year on a weekly basis. We know that the Part D sponsors and their contracted pharmacy benefit managers (PBMs) submit significant amounts of data after the Part D payment reconciliation cut-off date. The data continues to be submitted well after 1 year of the notice of the initial payment determination. Given the volume of new data that we receive after the notice of the initial payment determination, we believe that it is necessary to conduct at least 1 global reopening for every contract year in order to accurately reconcile the prospective payment made to Part D sponsors with the corresponding actual costs reported by the Part D sponsor on the PDEs.

In addition, and subsequent to our decision not to finalize the proposal that CMS perform one reopening within 5 year of the notice of the initial payment determination, we are not finalizing our proposal to remove the current timeframes for a reopening described in § 423.346 (a)(1) through (a)(3), remove paragraph (b) describing good cause referred to in paragraph (a)(2), or modify paragraph (c) to eliminate the reference to ''good cause.'' In other words, Part D plan payment reopenings will continue to be conducted as described at the current regulation at § 423.346.

Comment: A commenter stated that experience would suggest that over the years since the Part D program's inception, we have all improved in our efforts at the reconciliation and reopening of the Part D financial books, and therefore, encouraged CMS to enforce a shorter reopening timeframe after plan year initial closure. Specifically, the commenter recommended that CMS decrease the amount of time that plan years remain not finally reconciled to 4 years, not 5 years. This commenter encouraged a shorter time frame than 5 years, because from financial and compliance perspectives, this commenter thought that it would be beneficial to have a true final ''closure'' of the plan year earlier rather than later, to reduce uncertainty and risk.

Response: We agree with the commenter that experience suggests that we have all improved our efforts at reconciliations and reopenings. We are also sympathetic to the Part D sponsors' desires to ''close'' a plan year. However, we are not finalizing the proposal that CMS will reopen one time within 5 years after the date of the notice of the initial determination to the Part D sponsors. As previously stated, we believe that the proposal, if finalized, may create difficulties for Part D sponsors to return overpayments that they identify and are required to report and return under § 423.360.

Comment: A commenter requested that CMS consider setting a time period for when global reopenings occur, so that the industry has some clarity and predictability around timing of the reopenings. This commenter thought that knowing when a reopening is expected would make planning for Part D sponsors and CMS much easier and more efficient.

Response: Although we are not finalizing the proposal to reopen one time within 5 years after the date of the notice of the initial payment determination to the Part D sponsors, we agree with the commenter that setting a time period for when global reopenings occur would provide clarity and predictability around timing of the reopenings. As our experience and efficiencies improve, we expect that the reopenings will fall into a predictable, yearly schedule. Based upon recent historical experience, we anticipate beginning the global reopening process for a benefit year 4 years after releasing the initial reconciliation reports. We, at our discretion, may conduct reopenings after this time to rectify overpayments or unexpected issues resulting from the initial reopening.

After consideration of the public comments we received, we are not finalizing the proposal that we will reopen one time within 5 years after the date of the notice of the initial payment determination to the Part D sponsors. Consequently, we are not finalizing our proposal to remove the current timeframes for a reopening described in § 423.346 (a)(1) through (a)(3), remove paragraphs (b) describing good cause referred to in paragraph (a)(2), or modify paragraph (c) to eliminate the reference to ''good cause.''

We did not receive specific comments on our proposal to modify § 423.346 to accommodate the Coverage Gap Discount Reconciliation. We proposed that, similar to the Part D plan payment reopening, the reopening for the Coverage Gap Discount would be conducted one time in a 5-year period. For the same reasons previously stated for the Part D plan payment reopening, we are not finalizing that the Coverage Gap Discount reopening be conducted once in a 5-year period. However, consistent with that proposal, we are incorporating the Coverage Gap Discount reopening into the reopening process described at § 423.346. Therefore, we finalize the Coverage Gap Discount Reconciliation reopening by modifying § 423.346(a) by adding the phrase ''or the Coverage Gap Discount Reconciliation (as described at § 423.2320(b))'' to the end of the introductory paragraph.

3. Payment Appeals (§ 423.350)

In our proposed rule, we proposed to revise § 423.350 to accommodate a Coverage Gap Discount Reconciliation appeals process under the same authority with which we established the Part D payment appeals process under section 1860D–15(d)(1) of the Act. Consistent with the Part D payment appeals process currently described at § 423.350, the proposed changes establish an appeals process where the final reconciliation of the interim Coverage Gap Discount Program (CGDP) payments may be subject to appeal. Consistent with the Part D payment appeals process, we also proposed to amend § 423.350(a)(2) to include information that is submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations. Also consistent with the Part D payment appeals process, we proposed that the request for a reconsideration of the Coverage Gap Discount Reconciliation must be filed within 15 days from the date of the final payment, which is the date of the final reconciled payment made under § 423.2320(b).

Based on the preceding, we proposed to revise § 423.350 by adding a new paragraph (a)(1)(v) to allow for an appeal of a reconciled coverage gap payment under § 423.2320(b), by revising paragraph (a)(2) to indicate that the payment information submitted to CMS and reconciled under § 423.2320(b) is final and may not be appealed, and by adding a new paragraph (b)(1)(iv) to define the timeframe for appealing the final reconciled payment under § 423.2320(b).

We received the following comment and our response follows:

Comment: A few commenters requested that CMS extend the proposed 15-day deadline to file a request for reconsideration to 30 days due to the complexity of the CGDP. A commenter noted that 30 days would be more consistent with the existing plan-to-plan process. Another commenter stated that the15-day deadline would result in more ''defensive'' appeal from plans attempting to protect their interest in payments prior to the expiration of the appeal period, even where the subject plan may not yet, at this time of appeal, conclude that any payment discrepancies were in fact the result of methodological errors. A commenter believed that the proposed 15-day deadline would increase the administrative burden for CMS in processing unnecessary appeals and impair the efficient use of plan resources, which raises overall plan administrative costs.

Response: We decline to modify § 423.350(b)(1) to extend the proposed 15-day deadline to file a request for reconsideration to 30 days for the CGDP. We believe that some commenters may think that the appeals process under § 423.350 is broader than it actually is. Section 423.350 describes the appeals process for the Part D payment reconciliation and, as we proposed, the Coverage Gap Discount Reconciliation. An appeal can be filed if a Part D sponsor believes that CMS did not correctly apply its stated payment methodology. An appeal for any other reason will be dismissed. If a sponsor identifies a data discrepancy, the sponsor would not file an appeal but would file a reopening request under § 423.346.

The Part D sponsors are in possession of the same data CMS uses to determine the Coverage Gap Discount Reconciliation. The Part D sponsors will have the data in advance of the reconciliation and can validate the data prior to the reconciliation. Therefore, we believe that the proposed 15-day deadline is an adequate time for a Part D sponsor to determine whether CMS has correctly applied its stated payment methodology and, if necessary, file a request for reconsideration.

After consideration of the public comments we received, we are finalizing § 423.350 as proposed.

4. Payment Processes for Part D Sponsors (§ 423.2320)

In our proposed rule, we proposed to amend § 423.2320 such that we will assume financial liability for the applicable discount by covering the costs of the quarterly invoices that go unpaid by a bankrupt manufacturer at the time of the Coverage Gap Discount Reconciliation described at

§ 423.2320(b). This will ensure that the Part D sponsors have the funds available to advance the gap discounts at the point of sale, as required under section 1860D–14A(c)(1)(A)(ii) of the Act. We also stated that we would file a proof of claim with the bankruptcy court to recover costs from the bankrupt manufacturer. We proposed that we would implement our policy by adjusting the Coverage Gap Discount Reconciliation for manufacturer discount amounts as they are reported on PDEs submitted by the submission deadline for the Part D reconciliation.

Based on the preceding, we proposed to add a new paragraph (c) to § 423.2320 to describe a process for accounting for quarterly invoiced amounts that go unpaid by a bankrupt manufacturer.

We received the following comment and our response follows:

Comment: Commenters strongly supported our proposal. One commenter requested that CMS expand upon the section to include scenarios other than bankruptcy.

Response: We appreciate the support expressed for our proposal. However, we will not be expanding § 423.2320(c) to include scenarios other than bankruptcy. We will cover the costs of unpaid quarterly invoices only in the event that a manufacturer becomes bankrupt and fails to pay the invoices. As stated in the proposed rule, if a manufacturer becomes bankrupt, we are concerned that a court will modify or reduce the amount of the civil money penalties (CMPs), rendering the CMPs ineffective for covering the cost of the invoices and leaving the Part D sponsor in the position of having to cover the costs of the gap discount. In all other scenarios, CMPs, described at § 423.2340, will cover the cost of the unpaid invoices.

In light of the comment that we received recommending that we expand our proposal to include scenarios other than bankruptcy, we clarify that this provision will apply only to adjust for quarterly invoices that go unpaid after the manufacturer has declared bankruptcy. As previously stated, in all other cases, CMPs will cover the costs of unpaid quarterly invoices.

Also, consistent with our proposal to adjust the Coverage Gap Discount Reconciliation amount of each of the affected Part D sponsors to account for the total unpaid quarterly invoiced amount owed to each of the Part D sponsors in the contract year being reconciled, we clarify in the regulation that we will only adjust the Coverage Gap Discount Reconciliation amount for unpaid quarterly invoices used for that particular Coverage Gap Reconciliation. Use of a particular set of quarterly invoices in a Coverage Gap Discount Reconciliation is consistent with our current process, and we are not modifying that process for the purposes of this provision. Therefore, we clarify that we will not adjust the Coverage Gap Reconciliation amount for unpaid quarterly invoices that are not specifically used in that contract year's Coverage Gap Reconciliation.

After consideration of the public comments we received, we are finalizing § 423.2320(c) as proposed, with the minor clarifications discussed.

5. Risk Adjustment Data Requirements (§ 422.310)

In addition to the provisions addressed in the May 23, 2014 final rule (79 FR 29847),[8] we proposed to align § 422.310 regarding submission of risk adjustment data with § 422.326 by making a change in paragraph (g); specifically, we proposed the deletion of the January 31 deadline in paragraph (g)(2)(ii) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. This would allow the risk adjustment data submission deadline to also function as the Part C applicable reconciliation date for purposes of § 422.326 on overpayment rules because § 422.326(a) refers to the annual final deadline for risk adjustment data submission as a date ''announced by CMS each year.''

In response to the January 10, 2014 proposed rule, we received approximately six pieces of correspondence from organizations and individuals regarding this specific proposal to replace the January 31 deadline with a date announced annually by CMS. We received the following public comments and our responses follow.

Comment: A few commenters supported CMS' proposal to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually, with the proviso that CMS' timing of this annual deadline always allow sufficient opportunity for organizations to make final data submissions. Several other commenters stated their concern about this proposed change in deadline, including a concern that CMS might announce a deadline earlier than January 31 in some years. These commenters requested that CMS clarify that the annual deadline would never be before January 31, and a few commenters suggested that the regulation state that the deadline is January 31 but may be extended. Finally, a few commenters requested that CMS not change the January 31 date to a floating date, in order to allow operational stability.

Response: Our goal for eliminating January 31 as the final risk adjustment data submission deadline was to align this deadline at § 422.310(g)(2)(ii) with the overpayment provisions in § 422.326, so that the final risk adjustment data submission deadline would also function as the Part C applicable reconciliation date set forth in the overpayment provisions. As noted in the proposed rule, in order to align with the overpayment provisions, each year we expect to announce a date that would accommodate the current subregulatory guidance that MA organizations review the monthly enrollment and payment reports they receive from CMS within 45 days of the availability of the reports. We make these reports available to MA organizations each month according to an operational schedule that we release each year. Therefore, we expect to announce a final risk adjustment data submission deadline that falls on or just after the conclusion of this 45-day period for the January payment, which would be about 6 weeks after the end of the payment year, and no earlier than the current January 31 deadline.

We do not expect the date of the annual final risk adjustment data submission deadline to vary much from year to year but we believe that providing flexibility in the regulation text is necessary to accommodate the operational routines of our systems.

In response to comments, we are finalizing our provision at § 422.310(g)(ii) with modification, stating that the final risk adjustment data submission deadline will be announced by CMS each year and will be no earlier than January 31.

C. Strengthening Beneficiary Protections

1. MA–PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112)

Under § 422.112(b) of the MA program regulations, coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers. We believe that an important aspect of

[8] We proposed three amendments to § 422.310 in our January 10, 2014 proposed rule. In the May 23, 2014 final rule, we finalized one proposal, stated that we would not finalize the second proposal, and would finalize the third proposal at a later time. (See the May 23, 2014 final rule (79 FR 29848, 29925, and 29926). The third proposal is addressed in this final rule.

this coordination is ensuring that all needed services, including drug therapies, are provided in a timely manner. Certain drug classes, including certain infusion agents, oral anticancer therapies, oral anti-emetics, immunosuppressants, and injectables, may be covered by Part D only when coverage under Parts A or B is not available. Because coverage of these drugs cannot generally be determined based solely on the drug, plan formularies often apply prior authorization criteria before claims can be paid at the point-of-sale (POS). Additionally, when an MA–PD plan issues an adverse Part D coverage determination because they have determined the drug is covered under Parts A or B, we expect MA–PD plans to ensure the drug is provided under the Parts A and B basic benefit.

In the January 2014 proposed rule, we proposed to add a new paragraph (b)(7)(i) to § 422.112 to require MA–PDs to establish and maintain a process to ensure that appropriate payment is assigned at the POS. In the preamble, we characterized this as a proposal to require MA–PDs to establish adequate messaging and processing standards with network pharmacies to achieve this goal.

We also proposed to add a new paragraph (b)(7)(ii) to § 422.112 to require that MA–PD plans issue the determination and authorize or provide the benefit under the applicable part (A, B or D)—which would require the MA–PD plan to proactively coordinate their enrollees' prescription drug coverage under Parts A, B and D—in order to ensure that enrollees receive Medicare covered prescription drugs as expeditiously as the enrollee's health condition requires. We stated in the preamble that if a denial under Part D is based on the existence of coverage under Parts A or B, the MA–PD plan should authorize or provide the drug under that other benefit without requiring the enrollee to make a subsequent request for coverage under that other benefit. Such determinations about the coverage of the drug would have to be provided in accordance with part 422, subpart M and part 423, subpart M, when a party requests a coverage determination.

We received the following comments on this proposal and our responses follow:

Comment: Beneficiary advocacy groups, some health plans, and pharmacy groups expressed their support for our proposal to strengthen coordination of benefit requirements applicable to MA–PD plans. Those commenters believe that requiring more appropriate messaging at the POS would decrease enrollees' confusion and serve to improve coordination of benefits.

One commenter urged CMS to adopt a policy to treat presentation of a prescription at the pharmacy counter by an enrollee as a request for a Part D coverage determination and the response from the plan as an initial coverage determination, giving the enrollee access to the appeals process. The commenter stated it is especially important for claims rejected at the POS under Part D because coverage may be available under Part A or Part B from the same MA entity, to be treated as a request for a coverage determination to avoid delays in access.

Another commenter stated that CMS' longstanding policy that presentation of a prescription at the pharmacy counter is not considered a request for a coverage determination may seem like CMS is requiring the enrollee to request an initial coverage determination twice, contrary to our statement in the proposed rule that enrollees should not have to make an initial request more than once. Furthermore, the comment states that many, if not most, plans do not choose to treat presentation of a prescription as a request for a coverage determination because the pharmacy is not a representative of the plan trained to accept such requests on the plan's behalf, including collecting all the necessary information from the enrollee, conveying it to the plan within the required timeframe, and documenting its activities in this regard.

Response: We appreciate the commenters' support for our proposal, but would like to clarify that we are not requiring MA–PDs to pay at the POS for all drugs that might be covered under Parts A, B or D in all circumstances, nor are we requiring plans to treat a POS claim transaction as a request for a coverage determination. As we have stated since the inception of the Part D program, neither the presentation of a prescription at the pharmacy, nor a POS claim transaction constitutes a coverage determination or a request for a coverage determination by the plan. If a rejected claim cannot be resolved at the POS, the Part D plan is required to transmit a code to the network pharmacy instructing the pharmacy to provide the enrollee with the standardized pharmacy notice that advises the enrollee of the right to request a coverage determination from the plan. A coverage determination request must be made directly to the Part D plan by the enrollee, the enrollee's representative, or the prescriber. Pharmacy staff does not have all of the information necessary to make a coverage determination on behalf of the plan.

Comment: A commenter requested that CMS clarify that it does not prevent pharmacies from accessing readily available information to assist with appropriate payment determinations at the POS.

Response: We would like to clarify that we do not prohibit pharmacies from using or transmitting to the MA–PD plan readily available information for purposes of determining appropriate payment at POS. This final rule does not change the guidance contained at section 20.2.2 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, (Rev 10, 2–19–10), with respect to readily available information accessed by the pharmacy. The MA–PD plan will have met appropriate due diligence standards under Part D and the regulations implemented via this final rule without further contacting a physician if necessary and sufficient information is provided on the prescription, and the contracted pharmacy is able to communicate this information to the sponsor to assist in assigning appropriate payment at the POS.

Comment: A few commenters requested that CMS extend this proposal to out-of-network pharmacies.

Response: We disagree with these commenters. Plans do not have an established relationship with out of network pharmacies and, therefore, applying this proposal to them would be impractical.

Comment: Most commenters expressed strong support regarding CMS' proposal to coordinate Parts A, B, and D drug coverage during the coverage determination process.

Response: We thank commenters for their support. We will continue to work with stakeholders to explore program enhancements that may be more uniquely suited for plans that offer both Parts A, B and D benefits. We are exploring the possibility for future subregulatory guidance on this topic.

Comment: Several commenters suggested that CMS work with the Congress to simplify Medicare drug coverage by establishing clearer and simpler rules such as covering all prescription drugs under Part D instead of having coverage also under Parts A and B. Furthermore, a commenter urged CMS to consider using its regulatory authority to achieve some simplification by, for example, covering exclusively under Part D all drugs that are currently covered under Part D in the vast majority of cases.

Response: We appreciate commenters' desire for simpler coverage policies for

Medicare-covered prescription drugs. However, as recognized in the comments, statutory changes would be needed to simplify coverage and payment rules, which is outside the scope of this rulemaking. We will evaluate what appropriate simplifications we may be able to make using current regulatory authority.

Comment: Many commenters stated that although they are supportive of CMS' intention to ensure that beneficiaries are able to obtain their prescriptions without the inconvenience and delays that are due to differences in the coverage rules for drugs under Parts A, B, and D, there are going to be circumstances that require the enrollee or someone on the enrollee's behalf to request a coverage determination from the MA–PD. They suggested that CMS revise the proposed rule language to recognize that ''timely'' adjudication might not, and often cannot, occur at the POS because information that is essential to determining whether a drug is covered under Parts A or B often is not available at the POS and must be obtained from the prescriber and sometimes an organization determination also is required from the MA–PD. Pharmacy groups say they follow up with prescribers and MA–PDs, but delays are inevitable when those steps have to be taken.

Response: As indicated in the proposed rule, our intention is to add proposed § 422.112(b)(7)(i) to our regulatory provisions in an effort to improve at the POS the care continuity and coordination between Part D drug benefits and Parts A and B drug benefits administered by the MA–PD, not to establish a requirement that pharmacies be responsible for making coverage determinations. Although plans have the discretion to treat POS transactions as coverage determinations, it is our understanding that network pharmacies do not receive all of the information needed to act on behalf of hundreds of Part D sponsors in making robust coverage determinations and generating the required denial notice with detailed formulary information and appeal rights. Additionally, the current HIPAA transaction standards do not support the type and volume of information that would be necessary to treat POS rejections as adverse coverage determinations.

We realize that there will be circumstances in which the information necessary to determine whether a drug that is not covered under Part D would be covered under Parts A or B will not be available at the POS. In those cases, enrollees will receive the standardized pharmacy notice that explains the right to contact the plan for a coverage determination. However, we do believe that MA–PDs, by working with their network pharmacies and prescribers, are capable of a high degree of coordination and continuity. Through those collaborative efforts, the network pharmacy can often acquire information needed to obtain an edit override from the plan or otherwise ensure that the claim can be processed and paid at the POS.

Comment: Some commenters suggested that CMS adopt use of specific prior authorization codes, increased interoperability across electronic systems, and changes to Medicare's Common Working File (CWF) in order to make drug coverage determinations possible at the POS and decrease billing errors.

Response: We appreciate those suggestions and expect that MA–PDs and their network pharmacies will explore enhancements to their systems to improve communications and otherwise streamline their processes in order to ensure timely and accurate processing of POS transactions. We welcome suggestions for appropriate approaches that would support such improvements but decline to adopt rules to that effect at this time.

Comment: A few commenters stated that CMS' proposal to have plans pay for a drug and subsequently chase the responsible party for reimbursement would be inefficient and costly.

Response: We clarify for those commenters that neither our proposed nor this final rule include any provision that will require MA–PDs to pay for or cover a drug for an enrollee when another payor is responsible for that payment, or when a payment determination cannot be made at the POS. We agree that a ''pay and chase'' policy would not be efficient, and is not always in the best interest of the enrollee. As we discussed in the proposed rule, implementing a requirement to authorize all claims at the POS may interfere with medically appropriate pre-authorization requirements and may trigger retrospective enrollee liability depending on the difference in enrollee cost-sharing for coverage under Parts A, B, and D, retrospective TROOP adjustments and Part D reconciliation (79 FR 2009). We are finalizing the proposal to require MA–PDs to coordinate with their network pharmacies and prescribers to improve existing processes and develop new ones in order to ensure that enrollees receive their Medicare-covered prescribed medications, without delay, when they present at the network pharmacy.

After considering the comments, we are revising § 422.112(b)(7)(i) by deleting the reference to ''claims adjudication'' so there is a clearer distinction between the POS requirements addressed in paragraph (b)(7)(i) from the coverage determination requirements referenced in paragraph (b)(7)(ii). We are finalizing paragraph (b)(7)(i) to state that MA–PD plans must establish and maintain a process to ensure timely and accurate POS transactions. Compliance with this requirement may be achieved using adequate messaging and other procedures with network pharmacies to ensure care continuity and coordination at the POS between Part D drug benefits and Parts A or B drug benefits administered by the MA–PD.

When processing a coverage determination for a prescription drug that may be covered under Parts A, B or D, if the MA–PD determines, as part of the coverage determination process, that the requested drug is not covered under Part D, it must then evaluate whether the drug in question is covered under Parts A or B. The MA–PD is responsible for providing a clear explanation of its decision, including the decision to cover the requested drug under a different benefit and how to obtain the drug (for example, instructions to take the plan decision notice to the pharmacy to obtain the requested drug) in the Part D standardized denial notice. We expect to work with stakeholders to explore program enhancements that may be more uniquely suited for plans that offer both Parts A, B, and D benefits. We are finalizing, as proposed, § 422.112(b)(7)(ii) and are exploring possibilities for future subregulatory guidance on this topic.

2. Good Cause Processes (§§ 417.460, 422.74 and 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that MA organizations may terminate the enrollment of individuals who fail to pay basic and supplemental premiums after a grace period established by the plan. Section 1860D–1(b)(1)(B) of the Act generally directs us to establish regulations related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851 of the Act. In addition, section 1860D–13(a)(7) of the Act mandates that the premiums paid by individuals with higher incomes be increased by the applicable Part D income related monthly adjustment amount (Part D IRMAA), for the months in which they

are enrolled in Part D coverage. Consistent with these sections of the Act, subpart B in both the Part C and Part D regulations sets forth requirements with respect to involuntary disenrollment procedures at § 422.74 and § 423.44, respectively. An MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate that it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary a period of no less than 2 months in which to resolve the delinquency, and advising the beneficiary of the termination of coverage if the amounts owed are not paid by the end of the grace period.

In addition, current regulations at § 417.460(c) specify that a cost plan, specifically a health maintenance organization (HMO) or competitive medical plan may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. With the exception of the grace period, the procedural requirements for cost plans to disenroll a member for failure to pay premiums are similar to those for MA and Part D plans. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount and sent the enrollee written notice of the pending disenrollment at least 20 days before the disenrollment effective date.

In the April 2011 final rule (76 FR 21432), we amended both the Parts C and D regulations at § 422.74(d)(1)(v), § 423.44(d)(1), and § 423.44(e)(3) regarding involuntary disenrollment for nonpayment of premiums or Part D IRMAA to allow for reinstatement of the beneficiary's enrollment into the plan for good cause. In the April 2012 final rule (77 FR 22071), we extended the policy of reinstatement for good cause to include beneficiaries enrolled in cost plans in § 417.460(c)(3), thus aligning the cost plan reinstatement provision with the MA and PDP provisions. These good cause provisions authorize us to reinstate a disenrolled individual's enrollment without an interruption in coverage in certain circumstances where the non-payment was due to circumstances that the individual could not reasonably foresee or could not control, such as an unexpected hospitalization. Since its inception, the process of accepting, reviewing, and processing beneficiary requests for reinstatement for good cause has been carried out exclusively by CMS. However, we have received feedback from plans on ways to improve the good cause process and make it more efficient for both the plans and CMS. Based on this feedback, we updated Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual to clarify the language of the notice provided to beneficiaries, and the process and timing of receiving payments during the extended grace period in connection with § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi). In addition, we updated the Complaints Tracking Module (CTM) Standard Operating Procedures (SOP) to permit plans to transfer requests for reinstatement for good cause to CMS.

In light of ongoing feedback, in the January 2014 proposed rule we proposed to amend § 417.460(c)(3), § 422.74(d)(1)(v), and § 423.44(d)(1)(vi) to permit an entity acting on behalf of CMS to effectuate reinstatements when good cause criteria are met. This proposal would allow us to designate another entity, including a plan (MA organization, Part D sponsor, or entity offering a cost plan) to carry out portions or all of the good cause process. While we envisioned an expanded role for plans to accept incoming requests for reinstatement directly from former enrollees, which would allow them to be more responsive to their current and former members, we stated that ensuring objectivity in the review of these cases and equity among beneficiaries regarding the determination of good cause was critically important. Accordingly, we indicated that we would establish operational policy and processes in subregulatory guidance to set parameters for the application of the good cause standard, including the submission to us of certain cases for review to ensure that plans remain impartial and equitable in their assessment and treatment of former members who have been disenrolled for nonpayment of premiums. These changes would be accompanied by the development of an oversight protocol for any activities assigned to a designee that are currently carried out by CMS.

In addition, we proposed a technical change to the language in § 417.460 to clarify that good cause protections for enrollees in cost plans apply to instances where there was a failure to pay either plan premiums or other charges.

We received the following comments and our responses follow:

Comment: Commenters expressed both support for and opposition to our proposal to allow an entity acting on behalf of CMS to effectuate reinstatements when it is determined that good cause criteria are met. Several commenters agreed that plans or an independent contractor could perform this function if provided appropriate guidance and that this new process could produce efficiencies that would be advantageous to beneficiaries, plans and CMS. Other commenters believed that only CMS or an independent contractor would have the knowledge and impartiality to consider these cases appropriately. In addition, a few commenters expressed concerns with the quality of work currently performed by plans and CMS contractors and did not believe that their current performance warranted an increase in responsibility.

Response: We thank commenters for their feedback in response to this proposal. We continue to believe that with proper guidelines, instructions and oversight, entities to which we assign this activity could review and process good cause requests in an appropriate manner. Given the feedback we have received since establishing the good cause review process handled exclusively by us, we have learned that some good cause reinstatement requests could be resolved more efficiently by plans since they can readily access a former enrollee's premium billing and payment history, and as such, are well positioned to more easily resolve disenrollment disputes that are erroneously being treated, at least initially, as good cause requests.

We fully understand that impartiality would be a key concern if this function is performed by plans. That is why we noted in the January 2014 proposed rule that if we were to exercise the authority we proposed to include in these regulations, an oversight protocol would be developed and CMS would retain the right to review cases to ensure that determinations made by a CMS designee are in line with our guidance.

Comment: Under the assumption that plans would be given the responsibility to perform good cause reviews, a few commenters had questions about the plans' scope of responsibility. Specifically, a commenter questioned whether plans would be permitted to refer a case to CMS for review and decision. Another commenter questioned whether plans would be able to opt out of this work if they did not want to take on the burden or costs related to this activity. Lastly, a commenter questioned whether or not beneficiaries would be able to appeal the plan's decision.

Response: In the event we assign the good cause process to plans, the expectation would be that they perform the work from start to finish (that is, intake, research, decision, notification,

and effectuation). We would provide guidance regarding these activities in our enrollment manuals (Chapter 2 and Chapter 17, Subchapter D, of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual) and, as part of the designation, we would retain the authority to review both favorable and unfavorable decisions to ensure that results are fair and sound. In addition, as mentioned previously, we would develop an oversight protocol to ensure that plans are compliant with our guidelines. As with other MA and Part D policies, we realize that sometimes plans need feedback or guidance from us to address certain unique issues. That would continue to be the case for good cause reviews, but the expectation would be that once we assign this process to plans, they would develop their own internal processes for reviews, based on our guidance, and carry out the majority of this workload without involving us.

Beneficiaries do not currently have the right to appeal good cause determinations. Ultimately our goal is to streamline the good cause review process and make it easier for all parties (beneficiaries, plans, and CMS) to navigate. As such, we believe that the key to any successful delegation of this work to the plans would be providing clear and complete guidance to plans, but not adding another layer of review to the process.

Finally, should we conclude that plans are appropriate entities to perform good cause reviews, we would assign this function to all plans, and under the revisions to the regulations being finalized here, we would require plans to accept this additional responsibility. Specifically, we are finalizing the revisions to the applicable regulations to provide that a third party to which CMS has assigned this responsibility, such as an entity offering a cost plan, a MA organization, or a Part D plan sponsor, may reinstate an enrollee based upon the good cause showing. We believe it would be more complicated operationally, and confusing to beneficiaries, if we did not implement a uniform process for handling requests for reinstatement.

Comment: A commenter expressed support for the proposed revision to include language regarding a cost plan enrollee's ability to request reinstatement for good cause not only for failure to pay premiums, but also for nonpayment of ''other charges'' including deductibles and cost-sharing.

Response: We thank the commenter for their support for this regulatory change and for confirmation of the need to expand this beneficiary protection to cost plan enrollees.

After careful consideration of these comments, we are finalizing the proposed amendments to the regulations with modifications to clarify that the third party to which CMS may assign this responsibility may be an MA organization, a Part D sponsor or an entity offering a cost plan.

3. MA Organizations' Extension of Adjudication Timeframes for Organization Determinations and Reconsiderations (§ 422.568, § 422.572, § 422.590, § 422.618, § 422.619)

Sections 1852(g)(1)(A) and 1852(g)(2) of the Act respectively require MA organizations to make all organization determinations on a timely basis, and to provide for reconsideration, or review, of organization determinations within a timeframe specified by the Secretary, but no later than 60 days from the date of receipt of the request for reconsideration. Section 1852(g)(3)(B) of the Act requires MA organizations to maintain procedures for expediting organization determinations and reconsiderations when a physician's request indicates that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function or when, in the case of an enrollee's request, the MA organization makes such a determination on its own. In expedited cases, the MA organization generally must issue its decision no later than 72 hours from receipt of the request. Section 1852(g)(3)(B)(iii) of the Act permits the Secretary to extend this 72-hour decision-making timeframe in certain cases.

Our existing regulations at 42 CFR part 422, subpart M, codify the procedures MA organizations must follow in issuing standard and expedited organization determinations and reconsiderations, including setting forth the required adjudication timeframes and the circumstances under which plans are permitted to extend those timeframes.

As we stated in the proposed rule (79 FR 2011), we believe the current language that permits extension of the adjudication timeframes set forth in § 422.568(b), § 422.572(b), § 422.590(a)(1), and § 422.590(d)(2) is being interpreted more broadly than we intended and that MA organizations are regularly invoking extensions of the adjudication timeframes for organization determinations and reconsiderations. Based on information ascertained during recent MA program audits, we have seen circumstances in which MA organizations are routinely and inappropriately invoking the 14-day extension in cases where the plan: (1) Lacks adequate internal controls to ensure coverage requests are reviewed and adjudicated within the required regulatory timeframe; and (2) is awaiting receipt of supporting clinical documentation from one of its contract providers.

Routinely invoking an extension of the applicable adjudication timeframe is counter to the intent of the statutory and regulatory requirements for timely determinations that emphasize the health needs of the beneficiary in determining the appropriate adjudication timeframe. Extensions that are not affirmatively requested by the enrollee should be permitted only in limited circumstances, and only if the extension is in the enrollee's interest. MA organizations are required by regulation to render all coverage decisions as expeditiously as the enrollee's health condition requires. When plans choose to subject an item or service to a prior authorization requirement, we expect them to have the resources to process those requests in a timely manner.

In the proposed rule, we suggested revising these regulatory provisions to clarify our intended standard for when it is appropriate for an MA organization to extend an adjudication timeframe. Specifically, we proposed the following changes:

- At § 422.568(b), § 422.572(b), and § 422.590(e), to add new text and to restructure the regulation paragraphs for clarity.
- At § 422.568(b)(1)(ii), § 422.572(b)(1)(ii), and § 422.590(e)(1)(ii), to clarify that an extension may be justified and in the enrollee's interest due to the need to obtain additional medical information, which may result in changing the MA organization's denial of coverage of an item or service only from a non-contract provider.
- At new § 422.568(b)(1)(iii), § 422.572(b)(1)(iii), and § 422.590(e)(1)(iii), to clarify that an extension of the adjudication timeframe may be permitted when the extension is justified due to extraordinary, exigent or other non-routine circumstances, and it is in the enrollee's interest.
- To make corresponding technical edits to subpart M to improve clarity in our guidance related to extensions and to remove duplicative language (that is, to remove § 422.590(d)(2) and add a new § 422.590(e), to update cross references in § 422.618(a)(1) and § 422.619(a), to make changes within § 422.568(b), § 422.572(b), and § 422.590(d) to ensure

consistency in the structure and language of these provisions).

We received the following comments on this proposal and our responses follow:

Comment: Several commenters expressed general agreement that extensions to adjudication timeframes for organization determinations and reconsiderations should not be invoked routinely. Some commenters expressed strong support for this proposal and stated that it would reduce inappropriate delays in coverage decision-making and, therefore, reduce current delays in access to needed care that result from more routine use of extensions.

Response: We appreciate the support expressed by these commenters. The clarifications we proposed reinforce longstanding statutory and regulatory program requirements for timely decision-making that emphasize the beneficiary's health condition and the urgency of the requested item or service.

Comment: A few commenters who did not support the proposal stated that both contract and noncontract providers are not always responsive to plan requests for clinical information. A commenter further stated that MA organizations should not be penalized for delays resulting from third parties' failure to provide documentation necessary for a timely coverage decision. Another commenter added that it is not realistic to expect contract providers to produce complete medical documentation in response to every coverage request, and that it is not reasonable to expect provider contracting to ensure that full documentation is produced without the need for extensions. Because of those concerns, these commenters did not believe MA organizations should be restricted from using extensions on the basis of the provider's contracting status.

Response: We have considered contract providers as agents of the MA organization offering the plan, and we believe it is reasonable to expect MA organizations to use provider contracting to establish a wide range of expectations for network providers to ensure compliance with program rules, including timely receipt of relevant clinical documentation. MA organizations remain responsible for compliance with MA rules and requirements, even when using contractors or other entities to fulfill those responsibilities. (For more detailed information, see § 422.504(i)). We expect the contract terms between MA organizations and their contract providers to properly incentivize contract providers, as necessary, to produce requested clinical records in a timely manner.

We appreciate that health care providers working with managed care plans must navigate a complex and changing health care environment and routinely contract with multiple plans. However, we do not agree that these challenges should prevent MA organizations from rendering coverage decisions that are completed as expeditiously as the enrollee's health condition requires. The contractual arrangement with network providers is an important tool plans can use to ensure compliance with these beneficiary protections.

We expect plans to promptly solicit and obtain contract providers' clinical documentation when an enrollee requests coverage of an item or service. When the case file contains incomplete information, we expect plans to work diligently with contract providers to cure the defect while adhering to the requirement to issue all decisions as expeditiously as the enrollee's health condition requires. As stated previously and described in more detail later in this final rule, the new regulation text at § 422.568(b)(1)(iii), § 422.572(b)(1)(iii) and § 422.590(e)(1)(iii) clarifies that extensions are permitted—regardless of provider contracting status—if necessary clinical documentation is not readily available due to extraordinary, exigent or other non-routine circumstances.

We believe that plans can mitigate overuse of extensions by correcting other common compliance problems. For example, plans often receive audit findings for failure to conduct timely or sufficient outreach to providers to obtain necessary clinical information during the coverage determination process. Ensuring reasonable and diligent provider outreach will improve the plan's ability to issue timely decisions based on consideration of complete clinical information.

We expect plans to make reasonable, timely, and diligent efforts to obtain medical records from both contract and non-contract providers without having to extend the adjudication timeframe. However, we agree with the commenters that MA organizations have little control over a non-contract provider who does not respond to the plan's requests for documentation. For this reason, we are clarifying at § 422.568(b)(1)(ii), § 422.572(b)(1)(ii) and § 422.590(e)(1)(ii) that extensions are permitted when the plan is seeking clinical information from a noncontract provider, as long as the extension is in the enrollee's best interest. While we acknowledge this limitation, we nevertheless expect plans to make reasonable efforts to obtain necessary information from noncontract providers in a manner which affords the enrollee a timely decision.

We believe our proposed changes strike the appropriate balance between minimizing the burden on MA plans and providers (both contract and non-contract) and protecting enrollees' statutory right to timely decisions and to timely access to the appeals process.

Comment: A few commenters disagreed with our proposal because they believed that CMS was eliminating all extensions.

Response: It appears that these commenters misunderstood our proposed change. This change will not eliminate extensions. Extensions of up to 14 days will continue to exist for both standard and expedited requests for organization determinations and reconsiderations. As we stated in the proposed rule, we proposed these changes to clarify our existing intent that extensions at the MA organization's behest should only be taken on a limited basis and only when they are in the enrollee's interest.

Comment: Several commenters—both supportive and not supportive of CMS' proposal—noted that consideration of complete clinical documentation during the coverage decision process is in the best interest of the enrollee. Some of those commenters who disagreed with our proposal also stated that use of extensions to obtain missing clinical information when the plan is seeking that information is, therefore, also in the best interest of the enrollee. Likewise, some of these commenters expressed a belief that not taking an extension would be detrimental to enrollees by resulting in increased denials and delays in access to care.

Response: While we agree that it is in the best interest of an enrollee that the MA organization reviews complete clinical information when adjudicating a coverage request, we disagree with the commenters that use of extensions is in the best interest of the enrollee when such extensions are taken in the absence of extraordinary, exigent, or other non-routine circumstances. Section 1852(d) of the Act requires reasonably prompt access to medically necessary services—including compliance with provider network adequacy requirements established at § 422.112 of the regulations—and section 1852(g) of the Act requires timely coverage decisions that emphasize the health needs of the beneficiary in determining the appropriate adjudication timeframe. We do not believe that complete consideration of clinical documentation

and adjudication within the established timeframes are mutually exclusive activities. We established MA adjudication timeframes with strong support from stakeholders, including the managed care industry, and physician groups. (For a more detailed discussion, see the June 29, 2000 **Federal Register** (65 FR 40278)). Therefore, we do not believe that our proposed changes will cause a delay in access to care since MA organizations should be able to obtain the necessary information and render a decision within the established timeframes.

The new regulatory provisions at § 422.568(b)(1)(iii), § 422.572(b)(1)(iii) and § 422.590(e)(1)(iii) permits MA plans to invoke an extension in limited circumstances where timely receipt of necessary clinical information is not possible, for example, if a provider's office is flooded and additional time is needed to reach the provider and/or to obtain off-site or electronic records that would support a favorable coverage decision. We recognize that these extraordinary, exigent or other non-routine circumstances may arise regardless of whether the provider(s) involved has a contract with the plan; therefore, these extensions are not restricted to noncontract providers.

Comment: A commenter recommended that, instead of finalizing this proposal, CMS should use its existing oversight authority to take compliance or enforcement action against the MA organizations that over utilize extensions of adjudication timeframes.

Response: We agree with this commenter that imposing corrective action on MA organizations that are routinely noncompliant with required decision-making timeframes is an appropriate use of CMS' oversight authority, but we disagree that this should be done in lieu of our proposed changes. Based on recent program experience, we believe our intended restrictions from the original adoption of these rules on the use of extensions are broadly misinterpreted and that our proposed changes to clarify our policy will enhance beneficiary protections by reducing inappropriate delays in access to care and access to the appeals process.

Relying on compliance and enforcement authority alone is not a sufficient response to identification of a broadly misinterpreted policy. By clarifying our intent that extensions are appropriate only in a limited set of circumstances, we aim to assist MA plans in their development of operational policies and procedures related to processing coverage decisions and, ultimately, to meet our goal of overall program compliance in the absence of corrective action and the beneficiary risks that may come with it.

After consideration of the comments received on this proposal, and for the reasons noted in our January 2014 proposed rule, we are finalizing without modification the proposal to clarify that an extension to an adjudication timeframe for organization determinations and reconsiderations should be permitted only in limited circumstances.

D. Strengthening Our Ability To Distinguish Stronger Applicants for Part C and D Program Participation and To Remove Consistently Poor Performers

1. Two-Year Prohibition When Organizations Terminate Their Contracts (§§ 422.502, 422.503, 422.506, 422.508, and 422.512)

Section 1857(c)(4)(A) of the Act prohibits organizations from re-entering the MA program in the event that a previous contract with the organization was terminated at the request of the organization within the preceding 2-year period, except in circumstances that warrant special consideration.

We proposed to amend the text of the regulations implementing these provisions to maintain consistency in their application and harmony with our policy. Specifically, we proposed to amend the regulations at §§ 422.502(b)(3), 422.506(a)(4), and 422.512(e)(1) to explicitly apply the 2-year prohibition to applications for service area expansions in addition to applications for new contracts. These changes to §§ 422.502(b)(3), 422.506(a)(4), and 422.512(e)(1) would make the text of these regulations consistent with the text at §§ 422.503(b)(7) and 422.508(c) with regard to the 2-year prohibition imposed as a condition of a mutual termination of an MA contract.

We also proposed to amend our policy on the current application of regulations implementing the 2-year prohibition to avoid unnecessarily narrowing the scope of the 2-year prohibition or precluding us from preventing poor performing MA organizations from reentering the MA program. We proposed to interpret §§ 422.503(b)(6) and 422.503(b)(7) as authorizing denials of new contracts and service area expansions, consistent with the proposed text for §§ 422.502, 422.506 and 422.512, regardless of the contract type, product type, or service area of the previous nonrenewal. We further proposed adding a sentence to paragraphs (c) and (d) of § 422.508 to make it clear that a mutual termination of a MA contract would result in a ban on all contract types and service area expansions.

We received the following comments on this proposal and our responses follow:

Comment: A commenter supported the proposal, stating that it will prevent poor performing organizations from re-entering the program through another product type of extension of an existing service area.

Response: We thank the commenter for this support.

Comment: A commenter supported CMS's interpretation of the 2-year prohibition rule to voluntary nonrenewals and mutual terminations and CMS's efforts to ensure poor performing MA organizations do not re-enter the marketplace.

Response: We thank the commenter for this support.

Comment: A commenter requested that CMS consider only applying the 2-year prohibition to the legal entity level, rather than applying the 2-year prohibition to the parent organization level, as this would be an overly broad application which could affect multiple legal entities and numerous contracts.

Response: We currently apply the 2-year prohibition at the legal entity level and will continue to do so.

We are finalizing the amendments to §§ 422.502(b)(3), 422.506(a)(4), 422.508(c) and 422.512(e) as proposed. Although we discussed the amendments to § 422.508(c) and § 422.508(d) in the preamble to the January 6, 2014 proposed rule, we inadvertently omitted the proposed amendments to §§ 422.508(c) and 422.508(d) from the proposed regulation text. We are including the revision to § 422.508(c) in this final rule. We are not finalizing the proposed amendment to § 422.508(d) as upon further consideration we believe that this amendment is not appropriate. We are also amending § 422.506(a)(4) by removing the word ''special'' before ''circumstances warranting special consideration'' in order to maintain consistency with the regulation text at § 422.503(b)(6), § 422.508(c) and § 422.512(e), as we do not differentiate between circumstances warranting special consideration and special circumstances warranting special consideration in our administration of these regulations. We believe the use of ''special'' in § 422.506(a)(4) is redundant and its removal does not affect our interpretation of the provision and its inclusion potentially leads to ambiguity in § 422.506(a)(4). We are also finalizing, without modification, our proposal regarding the interpretation of

related regulations that implement the 2-year prohibition. We clarify here that the 2-year prohibition, for purposes of §§ 422.502, 422.506, 422.508, and 422.512, is applied at the legal entity level. We are further clarifying that the 2-year ban is applicable for the 2 contract years following the year in which the non-renewal or termination of an organization's contract is effective. For example, if an organization does not renew its contract for an effective date of December 31, 2015 then we would not enter into a contract with the organization for contract years 2016 and 2017 unless there are circumstances that warrant special consideration. The organization can apply to contract with us in contract year 2017 to operate in contract year 2018. Likewise, if an organization enters a mutual termination for a contract with CMS midyear during 2015, then we will not enter into a contract with the organization for contract years 2016 and 2017 absent circumstances warranting special consideration, but the organization can apply to contract with us in 2017 to operate in contract year 2018. We understand there are a variety of reasons that an organization may decide to terminate or to renew a contract, and subsequently want to re-enter the program. We will consider these circumstances on a case-by-case basis.

2. Withdrawal of Stand-Alone Prescription Drug Plan Bid Prior to Contract Execution (§ 423.503)

Occasionally, organizations new to Part D that have qualified for a Medicare PDP sponsor contract withdraw their bids after we have announced the low-income subsidy (LIS) benchmark but prior to executing the contract for the coming plan year. These withdrawals interfere with our administration of the Part D program, in particular the auto-assignment of LIS beneficiaries. To address this problem, we proposed to adopt regulatory provisions that would impose a 2-year application ban on organizations not yet under contract with us as PDP sponsors that withdraw their applications and bids after we have issued our approvals. We made this proposal under our authority at section 1860D–12(b)(3)(D) of the Act to adopt additional contract terms, including the conditions under which we would enter into contracts, not inconsistent with the Part D statute.

In February of each year, we solicit applications from organizations seeking to qualify to enter into a contract to offer stand-alone PDPs in the upcoming plan year. These organizations, along with current PDP sponsors who wish to continue participating in the Part D program, submit bids in June for our review and approval. We review these applications and bids with the expectation that, upon approval, the organizations would enter into PDP sponsor contracts with us in September to provide the Part D benefit for the plan year starting the following January.

As part of the annual bid review, we calculate the LIS benchmark for each PDP Region based on the bids for basic PDPs submitted annually by current PDP sponsors that will operate in that region in the coming year. Sponsors whose monthly premiums fall at or below the benchmark in a region receive auto enrollments from us of LIS eligible beneficiaries in those regions. We normally announce the LIS benchmark in late July or early August.

In recent years, some organizations have withdrawn their applications and bids following the announcement of the LIS benchmark. Because these organizations withdrew prior to executing a contract, and we cannot compel them to sign the contract, they are not subject to our compliance or oversight authority, and nothing in our current regulations prevents these applicants from withdrawing their applications late enough in the process to cause significant disruption. In contrast, when an existing PDP sponsor withdraws its bid, we treat such an action as an election by the PDP sponsor to non-renew its contract in that PDP Region, which renders the sponsor ineligible to submit another application for 2 years, under our regulations at § 423.507(a)(3). We proposed to make a regulatory change to ensure equal treatment between new applicants and existing PDP plan sponsors, which would allow us to maintain an accurate depiction of the contracting landscape. Specifically, we proposed to amend § 423.503 by adding paragraph (d) which would impose a 2-year Part D application ban on organizations approved by CMS as qualified to enter into stand-alone PDP sponsor contracts but which elect, after our announcement of the LIS benchmark, not to enter into such contract and withdraw their PDP bids. This proposed regulatory change, in effect, would subject a withdrawing applicant to the same penalty we may apply to an organization already under contract that elects to terminate or not renew its PDP contract.

It is critical that we have an accurate portrayal of the number and type of plan benefit packages that would be available to beneficiaries in every PDP Region, especially during the end of the summer when much of the bid review, both the formulary and actuarial components, has been completed. During this period, we need to confirm that there is the required minimum number of plans available in each PDP region. We also need accurate plan information at the end of the summer so that we can meet the production deadlines associated with the annual election period, including publication of the Medicare & You handbook as well as updating the Medicare Plan Finder Web site and our payment and enrollment systems. An applicant that withdraws its application late in the process alters the contracting landscape, potentially disrupting preparations we have already made, including those related to the auto assignment of LIS beneficiaries, for the upcoming plan year. In adopting the proposed regulatory authority, we would place a reasonable limit on prospective PDP sponsors' option to withdraw bids and applications without penalty. By imposing consequences on applicants that withdraw their bids following the announcement of the LIS benchmark, we also would discourage any ''gaming'' of the bid review and auto assignment processes (for example, by participating in the bid review process until it learns that it will not qualify for auto-assignments) that can occur when applicants opt out of participation in the PDP at the last minute.

We received the following comments and our response follows:

Comment: A number of commenters expressed support for CMS' proposal.

Response: We appreciate the commenters' support of our proposal.

We received only supportive comments for this proposal; therefore, we are finalizing this provision without modification.

3. Essential Operations Test Requirement for Part D (§§ 423.503(a) and (c), 423.504(b)(10), 423.505(b)(28), and 423.509)

We proposed to create, through regulation, an essential operations test, which will be a new step in the application and contracting process with newly contracted entities operating as stand-alone PDP sponsors or MA organizations offering Part D plans (MA–PDs). This step will be administered to ''newly contracted entities.'' We used the term ''newly contracted entity'' in the proposed rule and in this final rule to describe an organization that has entered or applied to enter into a Part D contract with us for the first time for the upcoming plan year, and neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current benefit year. This

would include organizations that are offering EGWPs for the first time. Existing plan sponsors or new sponsors that are subsidiaries of a parent company that currently operates a Part D plan through another subsidiary would not be subject to the proposed essential operations test.

The essential operations test will allow us to test whether an organization's arrangements appear likely to allow the organization to effectively administer its contract. We proposed to require organizations to pass an essential operations test either—(1) as a qualification to contract, with failure to pass the test nullifying our approval of the application; or (2) after contract execution as a contract requirement but prior to the start of the benefit year, with a failure to pass the test triggering an immediate contract termination under § 423.509.

Pursuant to section 1860D–12(b)(3)(D) of the Act, which incorporates by reference section 1857(e)(1) of the Act, we have the authority to add contract provisions that are necessary and appropriate to carry out the Part D program; section 1860D–11(b) of the Act provides authority for the collection of additional information as part of the bid as we may require to carry out the Part D program. Based on this authority we proposed adding § 423.504(b)(10) and § 423.505(b)(28) to include passing an ''essential operations test'' as a condition to enter into and a term of the Part D contract. Additionally, pursuant to our authority at section 1860D–12(b)(3)(B) and (b)(3)(F) of the Act (which incorporate by reference section 1857(c)(2) and (h) of the Act, respectively, to apply to the Part D program), the current regulations at § 423.509(a) and (b)(2)(i), authorize immediate termination of contracts with Medicare Part D plan sponsors in certain circumstances. We believe that immediate termination would be authorized under the standard of section 1857(h)(2) of the Act because the inability of a plan sponsor to ensure future members' access their drug benefit, as evidenced by failure to pass the essential operations test, would constitute an imminent and serious risk to beneficiary health and safety. We proposed adding § 423.509(a)(4)(xii) and revising § 423.509(b)(2)(i)(C) to subpart K to reflect this new cause for immediate termination. Additionally, we proposed to explicitly include the essential operations test as a means to evaluate Part D applicants in § 423.503(a)(1) and to add § 423.503(c)(4) to subpart K to establish failure of an essential operations test as grounds for nullifying our approval of the application notice.

Given that the heart of the Part D benefit is the sponsor's ability to process claims for prescription drugs in real time, we proposed the essential operations test and associated regulatory changes because of our experience with certain newly contracted entities in the Part D program that experienced significant operational difficulties at the start of the benefit year as a result of their inexperience administering Part D benefits. To prevent the recurrence of this problem and ensure that new sponsors are prepared to and actually can deliver Part D benefits at an acceptable level, starting with the 2015 contract year application cycle, we proposed that we may require newly contracted entities to pass an essential operations test conducted by us beginning in the fall of 2014. In response to the later anticipated date of the finalization of this provision, we expect to adjust our proposed timing and begin requiring newly contracted entities to pass an essential operations test with the 2016 contract year application cycle.

The essential operations test for newly contracted entities will entail testing of sponsors' command of Part D benefit administration rules and systems related to these areas. Initially, the testing will consist of scenario testing with sponsors' key staff to show us that they have a firm grasp of the Part D policies and essential operations. The test will be able to verify whether an applicant's administrative and management arrangements, as attested to in its application, are sufficient for the applicant to carry out functions listed in § 423.504(b)(4)(ii) such as furnishing prescription drug services and implementing utilization management programs.

Provided we have the resources, in the future, the test will likely become significantly more sophisticated and involve live testing of sponsors' systems with test data. The more involved test would also likely include testing the processes related to enrollment such as MARx communication and processing; LIS processing and determinations; coverage determinations, appeals, and grievances (CDAG) processing; and real-time coordination of benefits data exchange and processing. For instance, the sponsor would need to demonstrate the ability to pay test claims correctly in real-time consistent with its CMS-approved benefit packages (including formulary) and the Part D transition fill policy.

a. Failing Essential Operations Test as Cause for Immediate Termination

Once a sponsor signs its contract, it is obligated to perform all of the required functions to support the benefits described in the contract even though the sponsor does not start offering benefits until January 1. If we find that, based on the results of the essential operations test, a sponsor does not have the requisite systems and processes in place to offer Part D benefits in real time, our proposal was to consider this cause for immediate termination of the sponsor's Part D contract in order to protect beneficiaries from harm at the start of the contract year.

In accordance with section 1857(h)(2) of the Act (incorporated by reference into PDP by section 1860D–12(b)(3)(F) of the Act), we have the authority to immediately terminate a contract with a sponsor (without notice and opportunity for a hearing) when a delay in termination would pose an imminent and serious risk to the health of beneficiaries enrolled in the sponsor's plans. Also, under §§ 423.509(b)(2)(i) and 423.652(b)(2), unlike standard CMS terminations, the effective date of an immediate termination is not stayed when the sponsor requests a hearing under § 423.650(a)(2). Because enrollment and accurate benefit administration through real time claims processing are so fundamental to the delivery of the Part D benefit, if a sponsor fails to demonstrate to us that it can perform these essential operations, we would view this as a substantial failure to meet the Part D contract requirements on the following grounds: (1) Evidence that the sponsor was carrying out the contract in a manner that was inconsistent with the effective and efficient administration of the plan; and (2) evidence that the sponsor did not substantially meet the applicable conditions set out in the Part D regulations which would ultimately justify, depending upon timing of the test, our termination of a contract consistent with § 423.509(a)(1) through (3) based on the sponsor's failure to meet our proposed contract terms at § 423.504(b)(10) and § 423.505(b)(28). We believe that a newly contracted entity's failure to demonstrate certain critical capabilities and failing the essential operations test represents a substantial failure to carry out its Part D contract. Such a failure poses an unacceptable risk to the new sponsor's future members' access to Part D drugs, which would constitute an imminent and serious risk to beneficiary health and safety, justifying our immediate termination of the sponsor's contract.

For MA organizations that must offer Part D benefits pursuant to § 423.104(f)(3)(i), failing the test would support the termination of the organization's Part D addendum as well as its MA contract under § 422.510(a)(3) because the inability to offer Part D benefits means that the organization no longer meets the applicable conditions associated with offering Part C benefits.

b. Failing Essential Operations Test as Failure of a Qualification to Contract and Grounds for Nullification of Approval

If an organization fails an essential operations test we conducted prior to contract signature, we proposed that no termination would be necessary and that we would nullify our previous conditional approval of the organization's Part D contract qualification application. We proposed to explicitly include the essential operations test as a qualification to contract at § 423.503(a)(1) to authorize our use of the test and any information learned in the course of the essential operations test in making the contract determination.

We would view failure of the essential operations test as evidence that the applicant is not qualified to contract with us. As a result, we would nullify our approval based on determining the entity is not qualified. Successful applicants receive a conditional approval at the end of May of their Part D application in accordance with § 423.503(c)(1). The letter informs applicants that the conditional approval is based on the information contained in their application, and if we subsequently determined that any of the information was inaccurate or that qualification requirements are not met, we would withdraw the approval of the application. Through that notice, we preserve the right to nullify our approval. If that occurs, we would not provide the appeal rights described in part 423, subpart N to applicants that have their approval nullified based on failing the essential operations test because an appeals process started at that point could not be completed by the September 1 deadline imposed by § 423.650(c) for contracts to be effective on January 1 of the following year.

We received the following comments and our response follows:

Comment: Most commenters strongly supported CMS' proposals.

Response: We appreciate the support for these proposals.

Comment: Several commenters requested that CMS elaborate on the content of the essential operations test.

Response: Our plan is to initially offer the essential operations test in scenario format rather than in real time. Scenario format means that we will provide the applicant or newly contracted sponsor with written scenarios or stories about fictional beneficiaries. The scenarios will describe the characteristics of the beneficiary such as plan enrollment, LIS level, prior drug claims data, prior authorization criteria information, application date, and any other details necessary for answering our questions. The questions would pertain to topics such as determining the correct effective date of coverage; the appropriate timeframes for specific notifications; drug dispensing formats and requirements; drug coverage and costs; coverage determination process; coordination of benefits; and demonstrating knowledge of new requirements for the upcoming year. The real time test, which may also be combined with scenario tests, would involve electronic data exchanges between CMS and the new organization and/or its PBM, claims processor, enrollment processor, and any other entity contracted with the new organization to carry out key Part D functions.

Comment: Several commenters expressed concern that CMS would expect the new organization to demonstrate full system readiness in September. Other commenters provided information about the development schedule that their organizations follow for the upcoming benefit year.

Response: It is not our expectation that a new organization would have all systems ready to implement the Part D benefit in September. We appreciated the information regarding the development schedule, and we will use the information to inform, in part, our expectations of system readiness when we administer a real time test.

Comment: Several commenters requested that CMS provide new organizations with information about the system requirements of the essential operations test no later than May of each year.

Response: We are aware that new organizations would need time to ensure that the proper infrastructure is in place for real time communication and electronic data exchange with CMS (and our contractors). Therefore, within sufficient time to allow it to make necessary arrangements prior to the test, we will inform the new organization of the types of data files that we will send or exchange. We are unlikely to provide this information before the end of May because, at that time, new organizations will have not yet submitted bids. The essential operations test criteria may be developed based upon areas of concern we identify during the application, bid, and formulary review processes; therefore, in May we may not be certain of the test contents and parameters.

Comment: Several commenters suggested that CMS complete the essential operations test before November 1 due to the heavy workload in the last quarter of the year.

Response: We are aware of the heavy workload at the end of the year created by the annual election period and preparations for the start of the new benefit year. We will try to complete essential operations tests prior to November 1.

Comment: A commenter, a current Part D sponsor, was concerned that this provision would apply to existing or experienced sponsors.

Response: We clarify that this provision would not apply to existing sponsors. Rather, as stated at § 423.503(c)(4)(ii), the essential operations test will only be required of new organizations that do not have any Part D experience or a subsidiary/parent relationship with an experienced organization. If the new organization's parent company currently has other subsidiary organizations that are already offering Part D plans, then the new organization would not be subject to the essential operations test.

We note that the proposed provisions of §§ 423.504(b)(10) and 423.505(b)(28) each began with the phrase, ''Effective contract year 2015,''. This language, originally published in January 2014 as part of a proposal that at the time was expected to be made final in the middle of 2014, has since become outdated and therefore has been deleted from the final version of the rule. The proposed language was intended to make clear that even though the rule was expected to be finalized during the CY 2015 application review cycle we would apply the essential operations test to eligible applicants during that cycle. These provisions are now being made final after the period during which CY 2015 essential operations tests would have been conducted (that is, the fall of 2014). They will also be finalized well in advance of the start of the CY 2016 application cycle in late February 2015, so there is no need to provide a special signal to CY 2016 applicants that they may be subject to the essential operations test other than through the publication of this final rule.

We also note that we are finalizing with modification the proposed provision of § 423.505(b)(28). We are finalizing this provision as

§ 423.505(b)(27), instead of § 423.505(b)(28).

In summary, given the support for this proposal, we are finalizing these provisions with only the technical modifications described previously.

E. Implementing Other Technical Changes

1. Requirements for Urgently Needed Services (§ 422.113)

Many MA plans have responded to the need to provide urgently needed services outside of the network's business hours, for example, during the weekend or at night, by contracting with clinics that have hours of operation well beyond those of traditional physicians' offices to furnish services to their enrollees when the plan network is not available.

To better align the regulations with current practices regarding access to urgently needed care services, we proposed to revise the regulation by removing the phrase ''under extraordinary and unusual circumstances'' from the definition of ''urgently needed services'' at § 422.113(b)(1)(iii). The revised regulatory language would ensure that enrollees have access to out-of-network facilities in non-extraordinary circumstances.

We received the following comments on this proposal and our response follows:

Comment: Several commenters supported the policy because it provides improved access to enrollees.

Response: We thank these commenters for their support.

Comment: A commenter stated that CMS' proposed revision would be burdensome on plans and would not improve health care to enrollees.

Response: In the January 10, 2014 proposed rule, we noted that many plans already contract with clinics that operate 24 hours/day, 7 days/week (24/7) to address the needs of enrollees who need care on weekends or after normal business hours (79 FR 2018). We also noted that there are a small number of appeals each year from enrollees who sought care out-of-network on weekends or after normal business hours and were denied coverage.

We do not believe our proposal adds any burden to health plans. Our proposed revision to the regulation aligns it with current practices for provision of urgently needed services and our intent that enrollees have access to needed care. In fact, we believe that plans could realize savings by making urgently needed services available in settings that are more appropriate to the enrollees' needs than more costly hospital emergency departments.

Comment: A commenter expressed concern that the proposed regulatory language does not specify the circumstances under which the organization's provider network is temporarily unavailable or inaccessible and that, as a result, enrollees might frequently leave the network to obtain care.

Response: Circumstances under which the organization's provider network is temporarily unavailable or inaccessible would largely include weekends or after normal business hours, which we believe is clearly understood from the discussion in the notice of proposed rulemaking. If more extreme situations, such as a natural disaster, result in the network being temporarily unavailable, this rule would apply in those situations as well.

Comment: A commenter requested greater clarification of the definition of urgently needed services.

Response: The definition of urgently needed services, provided at § 422.113(b)(1)(iii), presents several specific requirements for a service to be classified as urgently needed. Additional clarification of the definition of urgently needed services may be found in the preamble to the June 29, 2000 final rule establishing the Medicare+Choice program (65 FR 40198 and 40199). We believe this definition, as modified by the removal of the phrase ''extraordinary and unusual circumstances,'' is sufficient.

After review of the public comments received, we are finalizing the proposed revision to § 422.113 without modification.

2. Agent and Broker Training and Testing Requirements (§§ 422.2274 and 423.2274)

We proposed to revise §§ 422.2274(b) and (c) and 423.2274 (b) and (c) to accomplish the following: (i) Remove CMS-endorsed or approved training and testing as an option; (ii) require that agents and brokers be trained annually on Medicare rules and regulations and details specific to the plan products they intend to sell; and (iii) require annual training to ensure appropriate knowledge and understanding of Medicare rules and specific plan products. Pursuant to our authority under sections 1851(h)(2), 1860D–1(b)(1)(B)(vi), 1851(j)(2)(E), and 1860D–4(l)(2) of the Act, we previously codified agent and broker training and testing requirements at §§ 422.2274 (b) and (c) and 423.2274 (b) and (c) to require all agents and brokers selling Medicare products be trained and tested annually through a CMS-endorsed or approved training program, or as specified by us, on Medicare rules and regulations specific to the plan products they intend to sell.

As we noted in the preamble to the proposed rule, since the training and testing requirements were implemented, we have embarked on various activities to improve and ensure the efficacy of training and testing. We also noted that, through our monitoring efforts, plans are complying with the annual guidance and providing an adequate level of detailed information. Furthermore, our ability to nationally accommodate agents and brokers through various training and testing modules creates a significant burden. We also noted in the preamble to the proposed rule that our ability to maintain consistency with endorsing other entities that would facilitate the training and testing and oversee these entities is limited.

We also proposed that the provisions for ''Reducing the Burden of the Compliance Program Training Requirements'' (§§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C)) require a standardized compliance training program and that, under those provisions, MA organizations and Part D sponsors would not be permitted to develop and implement plan specific training materials or supplemental materials. The requirement in this section is exclusive for agent and broker marketing activities under the MA and Part D program.

We received the following comments and our response follows:

Comment: A commenter supported the provision. However, the commenter requested clarification as to whether CMS will continue to provide annual guidance on training and testing requirements for agents and brokers.

Response: We appreciate the commenter's support and will continue to provide annual guidance on the training and testing requirements.

Comment: A commenter stated that the provision assigns responsibility for the annual agent/broker training to the MA organization, which is an operational burden and additional cost.

Response: We disagree. Since MA organizations and Part D sponsors currently facilitate the agent broker training and testing or contract with a third party, our proposal would not create an operational burden or cost.

Comment: A few commenters stated that this provision potentially conflicts with the proposed requirement under § 422.503 that MA organizations and Part D sponsors use only CMS training for general compliance. A commenter requested clarification on how the first

tier, downstream, and related entities' standardized training applies to agents and brokers.

Response: We believe that this provision does not conflict with the proposed provision in § 422.503. The provision in this section is specific to marketing activities for MA organizations and Part D sponsors.

After review of the public comment received on this proposed provision, we are finalizing this provision without modification.

3. Deemed Approval of Marketing Materials (§§ 422.2262, 422.2266, 423.2262, and 423.2266)

In the January 10, 2014 proposed rule, we proposed to move the substance of the current requirements in §§ 422.2266 and 423.2266 to 422.2262(a)(2) and 423.2262(a)(2), respectively. As previously noted, §§ 422.2266 and 423.2266 provide the regulatory requirements for materials that are deemed approved. These requirements are part of the review and distribution process of marketing materials. Therefore, the provisions were moved to align with the requirements in §§ 422.2262 and 423.2262. Additionally, we proposed reserving §§ 422.2266 and 423.2266 to further clarify the requirements for deemed materials by revising them to state that, if CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that an MA organization or Part D sponsor may use the material. We believe that this change clarifies the present regulatory requirement for deemed marketing materials.

We received several comments regarding this provision, and our responses follow.

Comment: Several commenters supported this provision. However, a few commenters did request clarification, while others emphasized the importance of streamlining the review and approval process for FIDE SNPs. A commenter also stated that CMS, Medicaid, and the plans should work closer to benefit enrollees.

Response: We thank the commenters for supporting our proposal to revise this provision. In response to the request for further clarification, we will consider including additional guidance in the Medicare Marketing Guidelines as that is the appropriate vehicle for providing detail on the requirements. We also appreciate the concerns with streamlining the review and approval process for FIDE SNPs; however, the comment is outside the scope of this rule.

Comment: A commenter opposed this provision on the grounds that MA organizations are expanding and offering more plan offerings with higher penetration rates in certain counties and regions. The commenter also stated that CMS is responsible for ensuring that marketing practices and materials are carefully monitored.

Response: While we appreciate the commenter's concern, we do not believe that the expansion of plan offerings will have an impact on this provision. Since this provision has been in existence, our analysis of deemed materials has shown that very few marketing materials have been approved through this process. Furthermore, we have protocols in place to monitor marketing materials, including materials that are deemed approved. We note in the Medicare Marketing Guidelines that we may require an MA organization or Part D sponsor to change any previously approved marketing materials if found to be inaccurate, altered or otherwise noncompliant.

After review of the public comments received on this proposal, we are finalizing this proposed provision without modification.

4. Cross-Reference Change in the Part C Disclosure Requirements (§ 422.111)

In the January 10, 2014 proposed rule, we proposed a technical correction to § 422.111(d)(1) to reflect the correct cross reference for procedures that MA organizations must follow when submitting changes to their rules for review. Section 422.111(d)(1) currently references § 422.80, which was removed when the marketing requirements were moved to subpart V, Medicare Marketing Requirements. We noted previously that subpart V, Medicare Marketing Requirements, was published in the September 18, 2008, final rule (73 FR 54208).

We received no comments on our proposal and therefore are finalizing this provision without modification.

5. Managing Disclosure and Recusal in P&T Conflicts of Interest: Formulary Development and Revision by a Pharmacy and Therapeutics Committee Under Part D (§ 423.120(b)(1))

Section 1860D–4(b)(3)(A)(ii) of the Act requires Part D sponsors who use formularies to include on their P&T committees at least one practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict with respect to the sponsor and the plan and who has expertise in the care of elderly or disabled persons. In our August 3, 2004 proposed rule (69 FR 46659), we proposed to interpret ''independent and free of conflict'' to mean that such P&T committee members could have no stake, financial or otherwise, in formulary determinations. In our January 28, 2005 final rule (70 FR 4256), we adopted this interpretation, and clarified that we would consider a P&T committee member not to be free of conflict of interest if he or she had any direct or indirect financial interest in any entity—including Part D plans and pharmaceutical manufacturers—that would benefit from decisions regarding plan formularies.

In a recent report (''Gaps in Oversight of Conflicts Of Interest in Medicare Prescription Drug Decisions,'' OEI–05–10–00450), the HHS OIG recommended improvements in our requirements for Part D plan P&T committees. Specifically, the OIG report recommended that we establish minimum standards to ensure that these committees have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts and to manage recusals due to conflicts of interests. The OIG report also suggested that we tell sponsors that they need to designate an objective party, such as a compliance officer, to flag and enforce the necessary recusals. In other words, the identification and evaluation of whether a disclosed financial interest represents a conflict of interest should be made by a knowledgeable and accountable representative of the sponsor's organization, such as the compliance officer, and not solely by the P&T committee members themselves. We concurred that P&T committees should have clearly articulated and objective processes to determine whether disclosed financial interests are conflicts, and to manage recusals arising from any such conflicts. Therefore, we proposed to revise our regulations at § 423.120(b)(1) to renumber the existing provisions and add a new paragraph (b)(1)(iv) to require that the sponsor's P&T committee clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i) through (iii) have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

We also solicited comment on the pros and cons of defining PBMs as entities that could benefit from formulary decisions from which one practicing physician and one practicing pharmacist on the P&T committee must be free of conflict of interest.

We received the following comments and our response follows:

Comment: A commenter noted that the current CMS formulary review process provides the necessary protections to beneficiaries and ensures that formularies are developed and managed in accordance with best practices. This commenter also pointed out that since the P&T committee members do not generally provide their services for free, it is standard practice that the PBM compensates the committee members for their committee-related activities; thereby, providing a financial conflict of interest. The commenter believes that without this financial compensation it would be difficult to engage qualified clinicians for the committee.

Response: While the compensation that P & T committee members receive from PBMs for performing committee-related activities could be seen as a potential conflict of interest, this practice is widely known and generally accepted as necessary to engage the most qualified clinicians. Moreover, we agree with the commenter that the current CMS formulary review process provides the necessary protections to beneficiaries and ensures that formularies are developed and managed in accordance with best practices. We have devoted extensive resources to the oversight of plan formularies and the audit of P&T committee proceedings to ensure that they comply with industry best practices and ensure beneficiaries' access to clinically appropriate therapies. As discussed more fully in the January 10, 2014 proposed rule (79 FR 2019), we believe that our current formulary review process confers appropriate protections to beneficiaries from any potential adverse effects of conflicts of interest.

The OIG report recommended that the P & T committee should have clearly articulated and objective processes to determine if disclosed financial interests are conflicts, and to manage any recusals if conflicts are found. We concur with this recommendation and proposed to revise our formulary requirements pertaining to the development and revision by a P & T committee at § 423.120(b)(1) to make it clear that the Part D sponsor must establish these processes. In our response to the OIG report, we noted that statutory and regulatory provisions (section 1860D–4(b)(3) of the Act and 42 CFR 423.120(b)) indicate that it is the plan's responsibility to meet the formulary requirements; which include the development of these processes.

Comment: Several commenters supported CMS' proposal that P&T committee processes must be clearly articulated, documented, and enforced by an objective party. However, a commenter requested that CMS better define the term ''objective party'' to include a knowledgeable and accountable person at the PBM.

Response: We agree with the commenter and clarify that the objective party may be a representative of the PBM, as long as that representative is not also a member of the sponsor's P&T committee. The objective party should be someone not on the P & T committee, and may include a representative from the PBM that is not on the P & T committee.

Comment: A commenter pointed out that while the proposed recusal process is logical, it is duplicative and the current P&T policy is sufficient for dealing with conflicts of interest.

Response: We disagree with the commenter and concurred with the OIG report's recommendation (as discussed in the January 2014 proposed rule) that P&T committees should have clearly articulated and objective processes to determine conflicts of interest and manage any recusals. We are implementing these requirements on the recommendation of OIG. These requirements are supplemental to the beneficiary protections outlined in existing P&T policy, which does not address recusal and only provides that committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

After review of the comments received, we are finalizing this provision without modification.

6. Thirty-Six Month Coordination of Benefits (COB) Limit (§ 423.466(b))

In our April 15, 2010 final rule (75 FR 19819), we exercised our authority under sections 1860D–23 and 1860D–24 of the Act to impose a timeframe on the coordination of benefits between Part D sponsors and other payers including State Pharmaceutical Assistance Programs (SPAPs), other providers of prescription drug coverage, or other payers. In the April 15, 2010 final rule, we explained our approach to determining the 3-year timeframe, including the benefits derived from its establishment.

We stated in our regulation at § 423.466(b) that, Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled. The phrase ''a period not to exceed 3 years'' has caused confusion among some sponsors, who interpreted this to mean that the coordination of benefits period could be shorter than 3 years and have consequently imposed tighter timeframes for coordination of benefits.

To clarify the requirement and avoid further confusion, we proposed to remove from the regulation the phrase ''not to exceed,'' and add the word ''of.'' This would clarify that sponsors must employ a coordination of benefits period of 3 years, and would remove any uncertainty about whether they may impose a shorter coordination of benefits period.

We also proposed to revise the heading of § 423.466 to reference claims adjustments, which are addressed in § 423.466(a).

Comment: A commenter indicated the proposed change was an appropriate modification.

Response: We appreciate the support for this provision.

Comment: A few commenters suggested we define the date on which the 3-year COB limit begins as the date the drug is dispensed or the first date of service.

Response: The regulation already specifies the 36-month period begins on the date the prescription for a covered Part D drug was filled. However, we note the date of fill as referenced in the regulation is synonymous with the NCPDP date of service (Field # 401–D1) included in HIPAA standard transactions, such as the billing transaction, and required on the Part D prescription drug event record.

After review of the public comments received in response to this proposal, we are finalizing the provision as proposed.

7. Application and Calculation of Daily Cost-Sharing Rates (§ 423.153)

We proposed technical changes to the daily cost-sharing rate regulation to clarify the application and calculation of daily cost-sharing rates and cost sharing under the regulations. Section 423.153(b)(4)(i) requires sponsors to establish and apply a daily cost-sharing rate whenever a prescription is dispensed by a network pharmacy for less than a 30-days' supply, unless the drug is excepted in the regulation. Currently, under § 423.100, in cases when a copayment is applicable, ''daily cost-sharing rate'' is defined as the monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount,

but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case. We proposed to replace the numbers with the phrase ''the number of days in the approved month's supply for the drug dispensed'' to address how Part D sponsors that have other days' supplies as their month's supplies are to calculate daily cost-sharing rates.

Also, under our existing definition of ''daily cost-sharing rate'' in § 423.100, as noted previously, and with respect to copayments, the daily copayment cannot be an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case. In other words, rounding up is not permitted under the current definition of ''daily cost-sharing rate'' and this has been another cause of confusion for some Part D sponsors. While our original intention was to prohibit significant increases in cost sharing, such as charging the full 30-day copay for both the trial supply and any subsequent refill of a medication, the current limitation on any increase in cost sharing over the 30-day supply amount has reportedly led to unnecessarily complicated programming, as well as proration of other amounts on the claim, such as the dispensing fees. Therefore, we proposed to replace the language ''lower dollar amount, if any, or to another amount,'' with ''the nearest cent.'' We believe this language better conveys the concept of rounding, while realizing this language allows Part D sponsors to round daily cost-sharing rates up or down to the nearest 2 decimal places.

We also proposed other technical changes to the daily cost-sharing rate regulation at § 423.153(b)(4)(i) to improve the regulation's clarity. First, we proposed to consolidate the language of § 423.153(b)(4)(i)(A) into § 423.153(b)(4)(i) and to consolidate § 423.153(b)(4)(i)(B)(1) and (2) into a new paragraph § 423.153(b)(4)(ii). Second, we proposed that the language in § 423.153(b)(4)(i) that addresses the application of the daily cost-sharing rate in the case of a monthly copayment be revised for clarity, and moved to a new paragraph (b)(4)(iii)(A). This paragraph states that in the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost sharing rate by the days' supply actually dispensed when the beneficiary receives less than a 30-days' supply. Third, we proposed that § 423.153(b)(4)(iii)(B) states that, in the case of a drug that would incur a coinsurance percentage, the Part D sponsor must apply the coinsurance percentage for the drug to the days' supply actually dispensed. We note that this means, with respect to dispensing fees, that the enrollee's portion of additional dispensing fees for the incremental supply is calculated by application of this percentage. These technical clarifications should assist sponsors in correctly setting, calculating, and applying daily cost-sharing rates in the retail and LTC settings whenever a prescription is dispensed by a network pharmacy for less than a 30-days' supply, unless the drug is excepted in the regulation. The proposal solicited comments on whether sponsors needed additional guidance surrounding the rounding methodology.

We received the following comments and our responses follow:

Comment: We received several comments in support of our proposal to clarify the daily cost sharing rule.

Response: We thank the commenters for their supportive comments on our proposal.

Comment: A commenter requesting that the application of the daily cost-sharing rule should be consistent with the changes CMS proposed to the definition of the ''daily cost-sharing rate.'' In other words, the commenter recommended that the daily cost-sharing rule apply whenever less than the approved month's supply is dispensed; rather than, whenever less than a 30-day supply is dispensed. The commenter highlighted that this change would ensure beneficiaries are not required to pay more than they otherwise would have. This is consistent with CMS' intent that even when the member does receive the remainder of a month's supply, the total payment not exceed the 1-month's cost sharing, except by a nominal rounding amount. This commenter provided the following example: A plan's approved month's supply is 34 days, and the applicable copayment is $30. If a member first obtains a 30-day supply and then a 4-day supply, under the current regulatory language, which provides that the daily cost-sharing rule applies when a covered Part D drug is dispensed for a supply less than 30 days, the member would pay $30 for the first supply since it is not for ''less than 30 days'' and then $3.52 (4 x $0.88) for the second supply, for a total of $33.52. However, if the daily cost-sharing rule applied whenever less than the approved month's supply is dispensed, the member would pay $26.40 (30 x $0.88) for the first supply and $3.52 (4 x $0.88) for the second, for a total of $29.92.

Response: We were persuaded by the comments that this suggested change is necessary to avoid confusion with the technical change that we proposed, by making the terminology consistent with the regulatory text. Therefore, we are making the following change to the final regulatory text: Replace ''30 days'' with ''approved month's supply'' in § 423.153(b)(4)(i) and (iii).

Comment: Several commenters indicated that CMS guidance is needed regarding the rounding methodology.

Response: We will provide additional rounding guidance, if needed, after publication of this final rule.

Based on comments received, we are finalizing this proposal as proposed and with the following modification: replacing ''30 days'' with ''approved month's supply'' where applicable in § 423.153(b)(4)(i) and (iii).

8. Technical Change To Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice (§ 423.562)

The current regulations at § 423.562(a)(3) require Part D plan sponsors to make arrangements with their network pharmacies to distribute notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception. This is accomplished through delivery of a standardized notice, CMS–10147—''Medicare Prescription Drug Coverage and Your Rights'' (''pharmacy notice''). Section 423.562(a)(3) cross-references § 423.128(b)(7)(iii), added in our April 2011 final rule (76 FR 21432), which requires plans to have a system in place that transmits codes to network pharmacies so the pharmacy is notified to deliver the pharmacy notice at the POS in designated circumstances where the prescription cannot be filled as written.

Pursuant to the 2011 regulatory change, we issued subsequent guidance (HPMS memoranda dated October 14, 2011 (''Revised Standardized Pharmacy Notice'') and December 27, 2012 (''Revised Guidance for Distribution of Standardized Pharmacy Notice'')) which clarifies that distribution of the pharmacy notice is required upon receipt of certain transaction responses indicating that the claim is not covered by Part D, as well as revised manual guidance in Chapter 18, section 40.3.1 of the Medicare Prescription Drug Benefit Manual related to operationalization of this requirement specific to a variety of specialty pharmacy settings.

In practice, we have never based distribution of or referral to the pharmacy notice on whether or not the

enrollee disagrees with information provided by the pharmacist, but rather on whether the drug in question can be provided under Part D and whether the enrollee is able to obtain coverage for the drug at the pharmacy counter. Because the existing regulation text at § 423.562(a)(3) ties delivery of the pharmacy notice to the enrollee's disagreement with information provided by the pharmacist, we proposed to remove this reference.

This proposed technical change would not alter the circumstances under which the pharmacy notice must be delivered to an enrollee and will align the regulation and the operational requirements for distribution of the pharmacy notice. In addition, this proposed change would be consistent with both the current OMB-approved instructions regarding the pharmacy notice and current CMS manual guidance.

We do not prohibit distribution of the pharmacy notice in any circumstance, so pharmacies may choose to also provide a copy of the notice in circumstances where the enrollee disagrees with the information provided (for example, if the enrollee believes they are being charged an incorrect cost-sharing amount), but the notice is not required under the standards established in § 423.128(b)(7)(iii). Provision of the pharmacy notice is not a prerequisite for an enrollee to request a coverage determination or access the appeals process. Similarly, a plan sponsor's failure to comply with the requirements of § 423.128(b)(7)(iii) or § 423.562(a)(3) does not in any way limit an enrollee's right to request a coverage determination or appeal.

We received no comments on this proposal and therefore are finalizing the proposed revision to this provision without modification.

9. MA Organization Responsibilities in Disasters and Emergencies (§ 422.100)

We proposed to add paragraph (m) to § 422.100 to codify and further clarify an MA organization's responsibilities when health plan services are affected by public health emergencies or disasters in order to ensure that beneficiaries continue to have access to care in situations in which normal business operations are disrupted due to public health emergencies or disasters and enable out-of-network providers to be informed of the terms of payment for furnishing services to affected enrollees during public health emergencies or disasters.

The proposed new paragraph would require MA organizations to ensure access, at in-network cost sharing, to covered services even when furnished by noncontracted providers when disruption in the service area impedes enrollees' ability to access contracted providers and/or contracted providers' ability to provide needed services. The new paragraph also provides the basis for determining the beginning and end of a disaster or emergency, and requires that the organization annually post on its Web site and notify enrollees and contracted providers of its disaster and emergency policies.

We received the following comments on this proposal and our response follows:

Comment: A commenter requested clarification of whether this proposed requirement applies if plan service delivery is not affected even though in a declared disaster area.

Response: Generally, a disaster creates multiple disruptions. For example, although provider offices may be operating as usual, transportation, electricity and phone service may be disrupted. Consequently, the proposed requirements would apply to all MA plans from the time the disaster is declared and continue to apply until the end of the disaster, as described in the proposed paragraph (m)(3).

Comment: Several commenters stated that the proposed revision should only apply to emergency and urgently needed services that are sought during a public health emergency or disaster.

Response: To the extent possible, we expect MA plans to provide continued and uninterrupted access to all health care services covered by the plan, whether routine or unforeseen. Disruption to a plan's network does not relieve an MA plan from fulfilling its contractual obligation to furnish all covered services to enrollees, even if it must do so by covering services furnished to its enrollees by noncontracted providers.

Comment: A commenter suggested that reduced out-of-network cost sharing be required only if contracted providers are unavailable or not accessible.

Response: Availability of networks depends on several factors—the status of provider offices, transportation, phone service, electric service, etc.—which may be impacted to varying degrees during a disaster. The primary goal during a disaster is the provision of continued and uninterrupted access of health care to all enrollees. To achieve this goal, enrollees must be allowed to obtain medically necessary plan-covered services without prior approval, at in-network cost sharing, from qualified providers, even if those providers are out-of-network.

Comment: A commenter stated that CMS should reconsider how this proposed regulation may manipulate enrollee incentives, reduce access for enrollees that need services more urgently and increase costs to MA organizations and the MA program.

Response: We recognize that disasters can create unavoidable disruptions and increased costs for MA organizations. Our primary goal during a disaster is the provision of continued and uninterrupted access to medically necessary plan-covered services for all enrollees. Our intention is to facilitate achievement of this goal by ensuring that plans facilitate increased access to providers from whom enrollees in the disaster area may seek high quality services at in-network cost sharing. We do not believe that these temporary and unusual episodes of increased access will incentivize enrollees in a negative way or result in significant cost increases for affected MA organizations.

After review of the public comments received on this proposal, we are finalizing the proposed provisions with modification. To provide for greater readability, we are finalizing paragraph (m)(1)(iii) with slight revisions to the text from the proposed version.

10. Technical Changes To Align Part C and Part D Contract Determination Appeal Provisions (§§ 422.641 and 422.644)

Sections 1857(h) and 1860D–12(b)(3)(F) of the Act describe the procedures for termination for both MA organizations and Part D Plan sponsors, respectively. These statutory provisions provide a contracting organization with an opportunity for a hearing before its contract is terminated. Appeal procedures were established under sections 1856(b)(2) and 1860D–12(b)(3) of the Act for both Part C and Part D sponsors, respectively. Sections 422.641 and 423.641 list the types of Part C and Part D contract determinations that may be appealed.

a. Technical Change (§ 422.641)

Currently in § 422.641, the contract termination is discussed in paragraph (b) and contract non-renewal is discussed in (c). Conversely, in § 423.641 the contract terminations are discussed in paragraph (c) and contract non-renewal is discussed in (b). Therefore, we proposed to align § 423.641 with the current list order for (b) and (c) in the contract determinations section at § 422.641.

b. Technical Changes (§ 422.644(a) and (b))

Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act describe the procedures for contract terminations for both MA organizations and Part D sponsors, respectively. In § 423.642(a) we specify that the notice is based upon a contract determination made ''under § 423.641.'' Therefore, since Part C and Part D language should be consistent, the same reference should be made in the corresponding Part C § 422.644(a). To remedy this, we proposed to insert ''under § 422.641'' into § 422.644(a) for Part C contract determinations.

In addition, the Part D plan sponsor language in § 423.642(b) states ''(b) The notice specifies the—(1) Reasons for the determination; and''. The corresponding Part C language in § 422.644(b) states that ''(b) The notice specifies—(1) The reasons for the determination; and''. We proposed to change § 422.644(b) by moving the word ''the'' and revising it to read ''(b) The notice specifies the—(1) Reasons for the determination; and''.

We received no comments on this proposal and therefore are finalizing these changes without modification.

11. Technical Changes To Align Parts C and D Appeal Provisions (§§ 422.660 and 423.650)

Sections 1857(h)(1)(B) and 1860D–12(b)(3)(F) of the Act provide organizations with an opportunity for a hearing before its contract is terminated in the Part C and Part D programs, respectively. Appeal procedures were established under section 1856(b)(2) of the Act for both MA organizations and Part D plan sponsors.

We proposed to replace the term ''under'' with the phrase ''in accordance with'' in § 422.660(a)(2), § 422.660(a)(3), and § 423.650(a)(2). We proposed to replace the word ''and'' with ''through'' in § 423.560(a)(4) to ensure consistency between § 422.660(a)(4) and § 423.650(a)(4). In addition, we proposed to modify § 422.660(b)(4) and § 423.650(b)(4) to add the language ''§ 422.752(a) through (b)'' and ''§ 423.752(a) through (b)'', respectively, to refer the reader to the applicable regulations for intermediate sanctions.

We received no comments on this proposal and therefore are finalizing this provision without modification.

12. Technical Change to the Restrictions on Use of Information Under Part D (§ 423.322)

We proposed a technical change to § 423.322 due to section 6402(b)(1) of the Affordable Care Act which amended section 1860D–15(f)(2) of the Act. For background, most of the payment provisions for the Part D program are found in section 1860D–15 of the Act, and as originally enacted, both subsections (d) and (f) authorized the Secretary to collect any information needed to carry out this section but also stated that information disclosed or obtained pursuant to section 1860D–15 of the Act may be used by officers, employees, and contractors of HHS only for the purposes of, and to the extent necessary in, carrying out section 1860D–15 of the Act.

Section 6402(b)(1) of the Affordable Care Act amended section 1860D–15(f)(2) of the Act to relax the limitation on the use of information that is disclosed or obtained under section 1860D–15 of the Act. Specifically, the Affordable Care Act removed the word ''only'' from subsection (f)(2)(A) and added a new subsection (ii) which states that information disclosed or obtained under section 1860D–15 of the Act may be used by officers, employees, and contractors of HHS for the purposes of, and to the extent necessary, in conducting oversight, evaluation, and enforcement under this title. Section 6402(b)(1) of the Affordable Care Act also added a new subsection (B) which states that information disclosed or obtained pursuant to section 1860D–15 of the Act may be used by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities. Thus, the Affordable Care Act considerably broadened the purposes for which HHS, its contractors, and the Attorney General and Comptroller General may use such information. However, we note, that the Affordable Care Act did not change the existing restriction on the use of information under subsection (d).

In light of the Affordable Care Act amendment to section 1860D–15(f) of the Act, we proposed to make conforming changes to § 423.322.

We received no comments regarding this proposal and are finalizing the proposed amendments to this provision without modification.

13. Technical Changes to Requirements Related to Qualified Prescription Drug Coverage (§ 423.104)

In the April 15, 2010 **Federal Register** (75 FR 19711), we finalized new requirements at § 423.104 related to qualified prescription drug coverage. At that time, we codified a new paragraph, § 423.104(d)(2)(iii) stating that tiered cost sharing under (d)(2)(ii) of the same paragraph may not exceed levels annually determined by CMS to be discriminatory. In the April 15, 2011 **Federal Register** (76 FR 21432), the language at (d)(2)(iii) was inadvertently removed when making other revisions to § 423.104.

To reinstate the language that was removed, we are including a technical change to add this language back to § 423.104. This technical correction does not represent a change in policy.

14. Technical Changes to the Definition of Supplemental Benefits (§ 423.100)

In the April 12, 2012 **Federal Register** (77 FR 22169), we revised the definition of supplemental benefits at § 423.100 by defining supplemental benefits as benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii). We subsequently issued a correction notice in the June 1 2012 **Federal Register** (77 FR 32407) with unrelated changes that inadvertently resulted in the revised definition not being included in the CFR.

To address this omission, we are issuing a technical change at this time to include the definition of supplemental benefits finalized in the April 12, 2012 **Federal Register** (77 FR 22169). This technical correction does not represent a change in policy.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (hereafter, ''PRA''), we are required to provide 30-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. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA 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 January 10, 2014, proposed rule (79 FR 1917) we solicited public comment on each of the following provisions that contained information collection requirements (ICRs).

A. ICRs Related to Eligibility of Enrollment for Individuals Not Lawfully Present in the United States (§§ 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, and 423.44)

As amended here sections 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, and 423.44 set out the eligibility requirement of citizenship or lawful presence to enroll in MA, Part D, and cost plans. To implement these provisions, we will: (1) Relay data regarding an individual's lawful presence status to plans through the MARx system so that the plans will be aware of an individual's eligibility when requesting enrollment; and (2) notify plans of loss of eligibility for current members based on unlawful presence status. In this final rule, we explicitly direct MA organizations, Part D sponsors, and entities offering cost plans not to request or solicit information about lawful presence from Medicare beneficiaries in connection with this rule as CMS will provide the necessary information. This data is already available to us; thus no new data will be collected.

We received no comments on the proposed ICR assessment. Consequently, we are finalizing that assessment without modification.

B. ICRs Related to Good Cause Processes (§ § 417.460, 422.74, and 423.44)

Sections 417.460, 422.74, and 423.44 establish the ability for us to designate an entity other than CMS to implement the good cause process. If we assign the good cause process to entities operating a cost plan, MA organization, or a Part D sponsor, the plan would already have the enrollment data necessary to make the determinations required by the process. In addition, the former enrollee is already required by the applicable regulations to provide a credible statement to establish good cause for the failure to make timely payments. Thus no additional data will be collected by the plan. However, if we designate plans to implement good cause processes, there would be additional burden to each plan. The burden would consist of completing the operational process, such as—(1) responding to requests for reinstatement from former members; (2) gathering the attestation from the individual regarding his or her reason for not paying the plan premiums within the grace period; (3) making the determination as to whether the individual meets the good cause criteria; and (4) maintaining the case notes and documentation to support its determination should it need to be reviewed. As plans already provide customer service to their current and past members, we estimate 30 minutes for each reinstatement request. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2013, the mean hourly wage for the category of ''Customer Service Representatives''—which we believe, considering the common point of entry for all issues at the plan, is the most appropriate category is $16.04/hr. With fringe benefits and overhead, the rate is $23.74/hr. It is calculated that the cost for 30 minutes would be $11.87. Not all plans disenroll for nonpayment of premiums. However, for those who do implement this voluntary policy, it results in an average of 20,000 disenrollments each month. In response, we receive an average of 698 requests for reinstatement per month. The plan representative cost of $11.87 for each case is multiplied by 698 cases. Therefore, under the revised regulations, handling of these requests would result in a total monthly cost of $8,285 (or $99,423 and 4,188 hours, annually) for all plans in the MA, Part D, and cost plan programs. The requirements and burden will be submitted to OMB under control number 0938—New (CMS–10544).

We received no comments on the proposed ICR assessment. Consequently, we are finalizing this assessment with only a minor modification in order to reflect the updated 2013 wage data.

C. ICRs Related To Expanding Quality Improvement Program Regulations (§ 422.152)

We explained in the proposed rule that we do not believe this provision would impose any new or revised collection requirements or burden because it codifies a submission process that currently applies for quality improvement program information. PRA approval is current under OMB control number 0938–1023 (CMS–10209).

We received no comments on the ICRs for this proposal and are finalizing these provisions without modification.

D. ICRs Related To Changes to Audit and Inspection Authority (§§ 422.503(d)(2) and 423.504(d)(2))

In §§ 422.503(d)(2) and 423.504(d)(2), MA organizations and Part D sponsors are required to hire an independent auditor to perform validation exercises to confirm correction of deficiencies found during an audit. We currently conduct these validation exercises and collect data associated with these activities under OMB control number 0938–1000 (CMS–10191). We believe the provision will not impose any additional burden on MA organizations or Part D sponsors.

E. ICRs Related to Business Continuity for MA Organizations and PDP Sponsors (§§ 422.504(o) and 423.505(p))

This provision requires MA organizations and Part D sponsors to develop, maintain, and implement business continuity plans that meet certain minimum standards. The proposed provision was modified due to public comment. Specifically, in this final rule MA organizations and Part D sponsors plan to restore essential operations within 72, rather than 24, hours of a failure. While the cost estimates are set out under this rule's Regulatory Impact Analysis, the PRA-related burden will be made available for public comment through a separate **Federal Register** notice under OMB control number 0938–0964 (CMS–10141).

F. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS' Web site at *http://www.cms.hhs.gov/PaperworkReductionActof1995;* email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov;* or call the Reports Clearance Office at 410–786–1326.

When commenting on the stated information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: *Mail:* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax:* (202) 395–5806, OR *Email: OIRA_submission@omb.eop.gov.*

PRA-related comments must be received on/by March 16, 2015.

IV. Regulatory Impact Statement

We examined the impact 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) and the Congressional Review Act (5 U.S.C. 804(2)).

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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We determined that this final rule does not reach the threshold for being considered economically significant, and thus, is not considered a major rule. There are five provisions with non-measurable impact: Efficient dispensing, requirements for drugs covered under Part D, two-year prohibition when organizations terminate their contract, requirements for urgently needed services, and MA organization responsibilities in disasters and emergencies.

Some of these provisions do not impose new requirements or costs but rather, clarify the necessary actions to meet existing regulatory requirements, and therefore, are expected to have no impact. Other provisions reflect widespread industry practices or would only impact a few plans and therefore are expected to have no, or minimal, impact.

There are three provisions with measurable impacts: Citizenship or lawful presence; audit and inspection authority; and business continuity operations. We discuss these three provisions as follows.

Citizenship or Lawful Presence. This final rule adds ''citizenship or lawful presence'' as an eligibility requirement to enroll and remain enrolled in MA, Part D, and section 1876 cost contracts to comply with section 401 of the Personal Responsibility and Work Opportunity Act, which mandates that aliens who are not lawfully present in the United States are not eligible to receive any federal benefit, including Medicare.

As indicated in the proposed rule of January 10, 2014 (79 FR 1918), based on estimates reflecting scoring by the CMS Office of the Actuary and 2012 lawful presence data provided by the SSA, this provision has an anticipated savings of $67 million over 5 years.

We estimate 10 million dollars expected savings for 2015 consisting of $5 million savings for Medicare Advantage (MA) and $5 million savings for Part D. These savings increase annually and by 2019, we estimate $17 million savings consisting of $8 million for MA and $9 million for Part D.

Audit and Inspection Authority. This rule finalizes some, but not all, proposed changes to the audit and inspection authority included in the proposed rule. We proposed two changes to §§ 422.503(d)(2) and 423.504(d)(2) that would allow CMS to require sponsors (MA organizations and Part D sponsors) to hire an independent auditor to conduct full or partial program audits of the sponsors' operational areas and/or correction validation exercises. Under the first proposal, each MA organization and/or Part D sponsor would have been required to hire an independent auditor to perform a full or partial program audit at least every 3 years. However, due to public comment, we are not finalizing this proposal.

We also proposed to revise our regulations to permit CMS to require MA organizations or Part D sponsors with audit results that reveal noncompliance with CMS requirements to hire an independent auditor to validate that correction has occurred. With our existing resources we currently conduct approximately 30 audits per year.

We received numerous comments indicating that our initial estimate was not accurate and considerably lower than the sponsors' actual costs. Based on the public comments, we revaluated our methods of estimating the sponsor costs associated with procuring an independent auditor to conduct validations and as a result we decreased: (1) The number of organizations that may be subject to a validation each year; and (2) the number of team members likely required to perform the validation exercise; and increased: (3) The estimated total cost per hour for the audit team. The estimate for 23 sponsors is closer to the maximum number of sponsors that would be expected to hire an independent auditor to validate correction of audit deficiencies that we identified. As additional organizations are subject to a CMS program audit or utilize CMS' audit protocols to perform their own internal auditing, we expect that the performance of these organizations and the industry in general will improve; this in turn will reduce the likelihood that an organization would need to hire an independent auditor to validate correction of audit deficiencies. Therefore, we expect the total number of organizations that may be required to hire an independent auditor to validate correction of audit deficiencies will decline over time.

While some sponsor audit findings can be validated through means other than a full-scale validation audit, we have found several organizations with significant performance deficiencies. We estimate that approximately 75 percent of the 30 organizations we audit per year (23 organizations) may be requested to retain an independent auditor to validate correction of their audit deficiencies.

Under these circumstances we estimated that the independent auditor hired would need to have a team consisting of the following professionals:

- Formulary and Benefits Administration—pharmacist, a senior claims analyst, and a senior auditor.
- Coverage Determinations, Part D Appeals, Part D Grievances—physician, pharmacist and senior auditor.
- Organization Determinations, Part C Appeals, Part C Grievances—physician, nurse practitioner, and senior auditor.
- Compliance Program effectiveness—two senior auditors.
- Special Needs Plan Model of Care (SNP MOC) implementation—nurse practitioner and senior auditor.

We used 2013 wage statistics supplied by the Bureau of Labor and Statistics, along with benefit and overhead included to develop estimates of direct wages. The estimated total cost per hour for each audit team is $1,202.00. A team of 13 professionals (listed previously) is necessary for the performance of each validation effort. The estimated total number of hours the team will need to perform the validation per sponsor is 80. The total cost per sponsor to procure and support the independent audit team is therefore: 80 (hours) × $1,202.00 = $96,160.00. The validation costs will be allowable costs in the plan's bid. Under existing regulations, the estimated total annual burden related to the time and effort for sponsors to perform the validation is $2,211,680.00 (23 sponsors × $96,160.00 per sponsor).

Since only 30 sponsors are audited per year and only those with the most serious findings would likely be subjected to hiring an independent auditor to conduct validation, the cost per sponsor per year is $2,211,680 ÷ 193 (unique parent organizations) = $11,459 per year. The number 193 represents the 193 unique parent organizations as of June 2014. This figure includes all coordinated care plans (CCPs), private fee for service (PFFS) plans, section

1876 Medicare cost plans whose parent organizations also have an MA or Part D plan, stand-alone prescription drug plans (PDPs), and employer group waiver plans (800 series). Sponsors will be allowed to account for this cost in their bid.

Business Continuity. Commenters in general took issue with the costs associated with the proposal for Business Continuity for MA organizations and Part D Sponsors (§§ 422.504(o) and 423.505(p)). Several commenters suggested that our RIA significantly underestimated costs because requiring MA organizations and Part D sponsors to restore essential functions within 24 hours would necessitate systems redundancy. Other commenters were concerned about the cost of testing IT systems on an annual basis; another commenter questioned the need to train ''all'' employees.

As detailed in section II.A.4. of this final rule (Business Continuity for MA organizations and Part D Sponsors (§§ 422.504(o) and 423.505(p)), we believe that the modifications to regulatory text that we are finalizing in this final rule, as well as clarifications provided in our responses (for instance, we are not requiring systems redundancy), address the vast majority of concerns raised about the RIA.

Business continuity plans are well established in the business community, and we believe that most MA organizations and Part D sponsors already have business continuity plans in place which cover the basic proposed subject areas. We still estimate that 5 percent of MA organizations and Part D sponsors do not have business continuity plans, but are updating our estimates from our proposed rule to reflect the most recent data available. For 2015, there are 568 MA organizations and Part D sponsors, resulting in an estimated 28 (5 percent × 568) affected entities. More recent May 2013 wage data from the BLS OES sets the hourly rate for an emergency management director, General Medical and Surgical Hospitals, at $36.90. We now estimate the first year burden of a full time emergency management director to help design the plan to be 58,240 hours (28 entities × 2,080 hours). The estimated cost associated with such an expert is the estimated number of hours multiplied by the estimated hourly rate of $36.90, plus 100 percent for fringe benefits and overhead, which equals a first year estimated cost of $4,298,112.

In subsequent years, the estimated burden associated with this requirement will be the cost of an emergency management director working on a part time basis for an ongoing burden of 29,120 hours (28 entities × 1,040 hours). The estimated cost associated with such an expert would be the estimated number of hours multiplied by the estimated hourly rate of $36.90 plus 100 percent for fringe benefits and overhead, which equals an estimated annual cost of $2,149,056 for subsequent years.

Additionally, as discussed in section II.A.4. of this final rule, we agree with the commenters that the regulation may require some changes, which we believe are minimal, to existing business continuity plans and are adding estimates to cover those costs. We estimate that an additional 10 percent of the 568 contracting entities, or about 57 entities, will be affected by this requirement. This means the estimated first year burden of a part time emergency management director to conform the existing business continuity plans will be 59,280 hours (57 entities × 1,040 hours). The estimated cost associated with such an expert is the estimated number of hours multiplied by the estimated hourly rate of $36.90 plus 100 percent for fringe benefits and overhead, which equals a first year estimated cost of $4,373,864.

In subsequent years, we estimate the burden associated with this requirement for MA organizations and Part D sponsors that are continuing to conform their business continuity plans with our regulation will decrease, for an ongoing burden of 29,640 hours (57 entities × 520 hours). The estimated cost associated with such an expert is the estimated number of hours multiplied by the estimated hourly rate of $36.90 plus 100 percent for fringe benefits and overhead, which equals a first year cost of $2,187,432.

Lastly, as previously discussed in our summary of the proposed effects, we believe that savings that we cannot capture will be realized by this regulation, especially for those MA organizations and Part D sponsors that do not currently have business continuity plans in place. Business continuity planning helps to protect resources and minimize losses. If as a consequence, MA organizations and Part D sponsors, that currently do not have these plans in place, provide Medicare benefits more efficiently after disasters and disruptions, this could result in fewer risks to beneficiary health.

Our analyses of the three provisions with measurable impact—unlawful presence, audit and inspection authority and business continuity operations—show that aggregate savings over 5 years is $33 million. Estimated savings for 2015 is $0 million and the savings increase annually to $11 million for 2019. Consequently, the savings do not reach the $100 million threshold and therefore this final rule is not a major rule.

The Regulatory Flexibility Analysis (RFA), as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

The health insurance industry was examined in depth in the RIA prepared for the proposed rule on establishment of the MA program (69 FR 46866, August 3, 2004). It was determined, in that analysis, that there were few, if any, ''insurance firms,'' including HMOs that fell below the size thresholds for ''small'' business established by the Small Business Administration (SBA). We assume that the ''insurance firms'' are synonymous with health plans that conduct standard transactions with other covered entities and are, therefore, the entities that will have costs associated with the new requirements finalized in this rule. At the time the analysis for the MA program was conducted, the market for health insurance was and remains, dominated by a handful of firms with substantial market share.

However, we estimate that the costs of this rule on ''small'' health plans do not approach the amounts necessary to be a ''significant economic impact'' on firms with revenues of tens of millions of dollars. Therefore, this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation proposed under Title XVIII, Title XIX, or Part B of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141

million. This final rule is not expected to reach this spending threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

List of Subjects

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 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as follows:

PART 417—HEALTH MAINTENANCE ORGANIZATION, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e-5, and 300e-9), and 31 U.S.C. 9701.

■ 2. Amend § 417.2 by revising paragraph (b) to read as follows:

§ 417.2 Basis and scope.

* * * * *

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act and 8 U.S.C. 1611.

* * * * *

§ 417.420 [Amended]

■ 3. Amend § 417.420, paragraph (a) by removing the phrase ''Individuals who are entitled to'' and adding in its place the phrase ''Eligible individuals who are entitled to''.

■ 4. Amend § 417.422 as follows:

■ a. In the introductory text, by removing the phrase ''any individual who—'' and adding in its place the phrase ''any individual who meets all of the following:''

■ b. In paragraphs (a) through (e), by removing the ''; '' and adding in its place ''.''.

■ c. In paragraph (f), by removing the ''; and'' and adding in its place ''.''.

■ d. Adding paragraph (h).

The addition reads as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *

(h) Is a United States citizen or an individual who is lawfully present in the United States as determined in 8 CFR 1.3.

■ 5. Amend § 417.460 as follows:

■ a. In paragraph (b)(2)(i) by removing ''.'' and adding in its place ''; ''.

■ b. In paragraph (b)(2)(iii) by removing ''; or'' and adding in its place ''; ''.

■ c. Redesignating paragraph (b)(2)(iv) as paragraph (b)(2)(v).

■ d. Adding a new paragraph (b)(2)(iv).

■ e. In paragraph (b)(3), by removing the cross-reference ''paragraphs (c) through (i)'' and adding in its place the cross-reference ''paragraphs (c) through (j)''.

■ f. By revising paragraph (c)(3).

■ g. In paragraph (c)(4), by removing the phrase ''non-payment of premiums.'' and adding in its place the phrase ''non-payment of premiums or other charges.''

■ h. By adding paragraph (j).

The revisions and the additions read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(b) * * *

(2) * * *

(iv) Is not lawfully present in the United States; or

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or a third party to which CMS has assigned this responsibility, such as an HMO or CMP) may reinstate enrollment in the plan, without interruption of coverage, if the individual shows good cause for failure to pay and pays all overdue premiums or other charges within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(j) *Enrollee is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h).

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 6. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 7. Amend § 422.1 by revising paragraph (a) to read as follows:

§ 422.1 Basis and scope.

(a) *Basis.* This part is based on the indicated provisions of the following:

(1) The following provisions of the Act:

(i) 1128J(d)—Reporting and Returning of Overpayments.

(ii) 1851—Eligibility, election, and enrollment.

(iii) 1852—Benefits and beneficiary protections.

(iv) 1853—Payments to Medicare Advantage (MA) organizations.

(v) 1854—Premiums.

(vi) 1855—Organization, licensure, and solvency of MA organizations.

(vii) 1856—Standards.

(viii) 1857—Contract requirements.

(ix) 1858—Special rules for MA Regional Plans.

(x) 1859—Definitions; enrollment restriction for certain MA plans.

(2) 8 U.S.C. 1611—Aliens who are not qualified aliens ineligible for Federal public benefits.

* * * * *

■ 8. Amend § 422.50 as follows:

■ a. In paragraph (a) introductory text, by removing the phrase '' if he or she—'' and adding in its place the phrase ''if he or she meets all of the following:''

■ b. In paragraphs (a)(1) and (4), by removing ''; '' and adding in its place ''.''.

■ c. In paragraph (a)(5), by removing ''; and'' and adding in its place ''.''.
■ d. By adding paragraph (a)(7).
The addition reads as follows:

§ 422.50 Eligibility to elect an MA plan.

* * * * *

(a) * * *

(7) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

* * * * *

■ 9. Amend § 422.74 as follows:
■ a. By adding paragraph (b)(2)(v).
■ b. By revising paragraph (d)(1)(v).
■ c. By adding paragraph (d)(8).
The additions and revision read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(v) The individual is not lawfully present in the United States.

* * * * *

(d) * * *

(1) * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as an MA organization) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual—

(A) Shows good cause for failure to pay within the initial grace period; and

(B) Pays all overdue premiums within 3 calendar months after the disenrollment date; and

(C) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(8) *Enrollee is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h) of this chapter.

* * * * *

■ 10. Amend § 422.100 by adding paragraph (m) to read as follows:

§ 422.100 General requirements.

* * * * *

(m) *Special requirements during a disaster or emergency.* (1) When a state of disaster is declared as described in paragraph (m)(2) of this section, an MA organization offering an MA plan must, until one of the conditions described in paragraph (m)(3) of this section occurs, ensure access to benefits in the following manner:

(i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3).

(ii) Waive, in full, requirements for gatekeeper referrals where applicable.

(iii) Provide the same cost-sharing for the enrollee as if the service or benefit had been furnished at a plan-contracted facility.

(iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3).

(2) *Declarations of disasters.* A declaration of disaster will identify the geographic area affected by the event and may be made as one of the following:

(i) Presidential declaration of a disaster or emergency under the either of the following:

(A) Stafford Act.

(B) National Emergencies Act.

(ii)(A) Secretarial declaration of a public health emergency under section 319 of the Public Health Service Act.

(B) If the President has declared a disaster as described in paragraph (m)(2)(i) or (ii) of this section, then the Secretary may also authorize waivers or modifications under section 1135 of the Act.

(iii) Declaration by the Governor of a State or Protectorate.

(3) *End of the disaster.* The public health emergency or state of disaster ends when any of the following occur:

(i) The source that declared the public health emergency or state of disaster declares an end.

(ii) The CMS declares an end of the public health emergency or state of disaster.

(iii) Thirty days have elapsed since the declaration of the public health emergency or state of disaster and no end date was identified in paragraph (m)(3)(i) or (ii) of this section.

(4) *MA plans unable to operate.* An MA plan that cannot resume normal operations by the end of the public health emergency or state of disaster must notify CMS.

(5) *Disclosure.* In addition to other requirements of annual disclosure under § 422.111, an organization must do all of the following:

(i) Indicate the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area.

(ii) Annually notify enrollees of the information listed in paragraphs (m)(1) through (3) and (m)(5) of this section.

(iii) Provide the information described in paragraphs (m)(1), (2), (3), and (4)(i) of this section on its Web site.

■ 11. Amend § 422.111 by revising paragraph (d)(1) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(d) * * *

(1) Submit the changes for CMS review under procedures of subpart V of this part.

* * * * *

■ 12. Amend § 422.112 by adding paragraph (b)(7) to read as follows:

§ 422.112 Access to services.

* * * * *

(b) * * *

(7) With respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D, MA–PD plans must coordinate all benefits administered by the plan and—

(i) Establish and maintain a process to ensure timely and accurate point-of-sale transactions; and

(ii) Issue the determination and authorize or provide the benefit under Part A or Part B or as a benefit under Part D as expeditiously as the enrollee's health condition requires, in accordance with the requirements of subpart M of this part and subpart M of part 423 of this chapter, as appropriate, when a party requests a coverage determination.

* * * * *

■ 13. Amend § 422.113 by revising paragraph (b)(1)(iii) introductory text to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(1) * * *

(iii) *Urgently needed services* means covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (or provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

* * * * *

■ 14. Amend § 422.152 as follows:
■ a. Revising paragraph (a) introductory text.

■ b. Redesignating paragraphs (a)(1) through (3) as paragraphs (a)(2) through (4), respectively.
■ c. Adding new paragraph (a)(1).
■ d. In newly redesignated (a)(2), by removing the ''; '' and adding a ''.''.
■ e. In newly redesignated (a)(3), by removing the ''; and'' and adding a ''.''.
■ f. Revising paragraph (c).
■ g. Revising paragraph (g) introductory text.
■ h. Revising paragraph (h).

The revisions and addition read as follows:

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization that offers one or more MA plan must have, for each plan, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must do all of the following:

(1) Create a quality improvement program plan that sufficiently outlines the elements of the plan's quality improvement program.

* * * * *

(c) *Chronic care improvement program requirements.* (1) Develop criteria for a chronic care improvement program. These criteria must include the following:

(i) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program.

(ii) Mechanisms for monitoring MA enrollees that are participating in the chronic improvement program and evaluating participant outcomes such as changes in health status.

(iii) Performance assessments that use quality indicators that are objective, clearly and unambiguously defined, and based on current clinical knowledge or research.

(iv) Systematic and ongoing follow-up on the effect of the program.

(2) The organization must report the status and results of each program to CMS as requested.

* * * * *

(g) *Special requirements for specialized MA plans for special needs individuals.* All special needs plans (SNPs) must be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. SNPs must submit their model of care (MOC), as defined under § 422.101(f), to CMS for NCQA evaluation and approval, in accordance with CMS guidance. In addition to the requirements under paragraphs (a) and (f) of this section, a SNP must conduct a quality improvement program that does the following:

* * * * *

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* MA PFFS and MSA plans are subject to the requirement that may not exceed the requirement specified in § 422.152(e).

■ 15. Amend § 422.310 by revising paragraph (g)(2)(ii) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(g) * * *

(2) * * *

(ii) After the final risk adjustment data submission deadline, which is a date announced by CMS that is no earlier than January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.

* * * * *

§ 422.502 [Amended]

■ 16. Amend § 422.502(b)(3) by removing the phrase ''CMS may deny an application based on the applicant's'' and adding in its place the phrase ''CMS may deny an application for a new contract or service area expansion based on the applicant's''.

■ 17. Amend § 422.503 by adding paragraph (d)(2)(iv) to read as follows:

§ 422.503 General provisions.

* * * * *

(d) * * *

(2) * * *

(iv) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

* * * * *

■ 18. Amend § 422.504 by adding paragraph (o) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(o) *Business continuity.* (1) The MA organization agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (o)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each MA organization must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraphs (o)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (o)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every MA organization must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the MA organization identifies under paragraph (o)(1)(ii) of this section, for purposes of this paragraph (o)(2) of the section essential functions include, at a minimum, the following:

(i) Benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service.

(ii) Operation of call center customer services.

■ 19. Amend § 422.506 by revising paragraph (a)(4) to read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(4) If an MA organization does not renew a contract under paragraph (a) of this section, CMS may deny an application for a new contract or a service area expansion from the MA organization for 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

* * * * *

■ 20. Amend § 422.508 by revising paragraph (c) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

* * * * *

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

* * * * *

■ 21. Amend § 422.512 by revising paragraph (e)(1) to read as follows:

§ 422.512 Termination of contract by the MA organization.

* * * * *

(e) * * *

(1) CMS may deny an application for a new contract or a service area expansion from an MA organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the contract type, product type, or service area of the previous contract.

* * * * *

■ 22. Amend § 422.568 by revising paragraph (b) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(b) *Timeframe for requests for service.* Except as provided in paragraph (b)(1) of this section, when a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(1) *Extensions.* The MA organization may extend the timeframe by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

■ 23. Amend § 422.572 by revising paragraph (b) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* (1) The MA organization may extend the 72-hour deadline by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

■ 24. Amend § 422.590 as follows:

■ a. By revising paragraph (a)(1).

■ b. In paragraph (d)(1), by removing the cross reference ''paragraph (d)(2) of this section'' and adding in its place the cross-reference ''paragraph (e) of this section''.

■ c. By removing paragraph (d)(2).

■ d. By redesignating paragraphs (d)(3) through (5) as paragraphs (d)(2) through (4), respectively.

■ e. By redesignating paragraphs (e) through (g) as paragraphs (f) through (h), respectively;

■ f. By adding paragraph (e).

The addition and revision read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) * * *

(1) Except as provided in paragraph (e) of this section, if the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30

calendar days from the date it receives the request for a standard reconsideration.

* * * * *

(e) *Extensions.* (1) As described in paragraphs (e)(1)(i) through (iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

(2) *Notice of extension.* When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

§ 422.618 [Amended]

■ 25. In § 422.618, amend paragraph (a)(1) by removing the cross-reference ''§ 422.590(a)(1)'' and adding in its place the cross-reference ''§ 422.590(e)''.

§ 422.619 [Amended]

■ 26. In § 422.619, amend paragraph (a) by removing the cross-reference ''§ 422.590(d)(2)'' and adding in its place the cross-reference ''§ 422.590(e)''.

■ 27. Amend § 422.641 by revising paragraphs (b) and (c) to read as follows:

§ 422.641 Contract determinations.

* * * * *

(b) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(c) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

* * * * *

■ 28. Amend § 422.644 by revising paragraphs (a), (b)(1), and (c)(1) to read as follows:

§ 422.644 Notice of contract determination.

* * * * *

(a) When CMS makes a contract determination under § 422.641, it gives the MA organization written notice.

(b) * * *

(1) Reasons for the determination; and

* * * * *

(c) * * *

(1) *General rule.* Except as provided in paragraph (c)(2) of this section, CMS mails notice to the MA organization 45 calendar days before the anticipated effective date of the termination.

* * * * *

■ 29. Amend § 422.660 by revising paragraphs (a)(2) and (3) and (b)(4) to read as follows:

§ 422.660 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) * * *

(2) An MA organization whose contract has been terminated in accordance with § 422.510.

(3) An MA organization whose contract has not been renewed in accordance with § 422.506.

* * * * *

(b) * * *

(4) During a hearing to review the imposition of an intermediate sanction as described at § 422.750, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752(a) and (b).

* * * * *

■ 30. Amend § 422.2262 by adding paragraph (a)(2) to read as follows:

§ 422.2262 Review and distribution of marketing materials.

(a) * * *

(2) If CMS does not approve or disapprove marketing materials within the specified review timeframe, the materials will be deemed approved. Deemed approved means that the MA organization may use the material.

* * * * *

§ 422.2266 [Removed and Reserved]

■ 31. Section 422.2266 is removed and reserved.

■ 32. Amend § 422.2274 by revising paragraphs (c) and (d) to read as follows:

§ 422.2274 Broker and agent requirements.

* * * * *

(c) *Annual training.* The MA organization must ensure that all agents and brokers selling Medicare products are trained annually on the following:

(1) Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

(d) *Annual testing.* It must ensure that all agents and brokers selling Medicare products are tested annually, to ensure the following:

(1) Appropriate knowledge and understanding of Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 33. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 34. Amend § 423.1 by adding paragraph (a)(3) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(3) Section 1611 of Title 8 of the United States Code regarding individuals who are not lawfully present and ineligible for Federal public benefits.

* * * * *

■ 35. Amend § 423.30 as follows:

■ a. In paragraph (a)(1) introductory text, by removing the phrase ''if he or she:'' and adding in its place the phrase ''if he or she does all of the following:''.

■ b. In paragraph (a)(1)(i), by removing ''; and'' and adding in its place ''.''.

■ c. By adding paragraph (a)(1)(iii).

The addition reads as follows:

§ 423.30 Eligibility and enrollment.

(a) * * *

(1) * * *

(iii) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

* * * * *

■ 36. Amend § 423.44 as follows:

■ a. Adding paragraph (b)(2)(vi).

■ b. Revising paragraph (d)(1)(vi).

■ c. Adding paragraph (d)(8).

The additions and revision read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(2) * * *

(vi) The individual is not lawfully present in the United States.

* * * * *

(d) * * *

(1) * * *

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as a Part D sponsor) may reinstate enrollment in the PDP,

without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within 3 calendar months after the disenrollment date. The individual must establish by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(8) *Individual is not lawfully present in the United States.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 423.30(a)(1)(iii).

* * * * *

■ 37. Amend § 423.100 by revising the definitions of ''Daily cost-sharing rate'' and ''Supplemental benefits'' to read as follows:

§ 423.100 Definitions.

* * * * *

Daily cost-sharing rate means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by the number of days in the approved month's supply for the drug dispensed and rounded to the nearest cent; or

(2) Coinsurance percentage under the enrollee's Part D plan.

* * * * *

Supplemental benefits means benefits offered by Part D plans, other than employer group health or waiver plans, that meet the requirements of § 423.104(f)(1)(ii).

* * * * *

■ 38. Amend § 423.104 by adding paragraph (d)(2)(iii) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(iii) Tiered cost sharing under paragraph (d)(2)(ii) of this section may not exceed levels annually determined by CMS to be discriminatory.

* * * * *

■ 39. Amend § 423.120 by redesignating paragraphs (b)(1)(iv) through (x) as paragraphs (b)(1)(v) through (xi), respectively, and adding paragraph (b)(1)(iv) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(1) * * *

(iv) Clearly articulates and documents processes to determine that the requirements under paragraphs (b)(1)(i) through (iii) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

* * * * *

■ 40. Amend § 423.128 by adding paragraph (g) to read as follows:

§ 423.128 Dissemination of Part D information.

* * * * *

(g) *Changes in rules.* If a Part D sponsor intends to change its rules for a Part D plan, it must do all of the following:

(1) Submit the changes for CMS review under the procedures of Subpart V of this part.

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period as defined in section 1860D–1(b)(1)(B) of the Act.

(3) Provide notice of all other changes in accordance with notice requirements as specified in this part.

■ 41. Amend § 423.153 by revising paragraph (b)(4) to read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

* * * * *

(b) * * *

(4)(i) *Daily cost sharing rate.* Subject to paragraph (b)(4)(ii) of this section, establishes a daily cost-sharing rate (as defined in § 423.100) and applies it to a prescription presented to a network pharmacy for a covered Part D drug that is dispensed for a supply less than the approved month's supply, if the drug is in the form of a solid oral dose and may be dispensed for less than the approved month's supply under applicable law.

(ii) *Exceptions.* The requirements of paragraph (b)(4)(i) of this section do not apply to either of the following:

(A) Solid oral doses of antibiotics.

(B) Solid oral doses that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging to assist patients with compliance.

(iii) *Cost-sharing*—(A) *Copayments.* In the case of a drug that would incur a copayment, the Part D sponsor must apply cost-sharing as calculated by multiplying the applicable daily cost-sharing rate by the days' supply actually dispensed when the beneficiary receives less than the approved month's supply.

(B) *Coinsurance.* In the case of a drug that would incur a coinsurance percentage, the Part D sponsor must apply the coinsurance percentage for the drug to the days' supply actually dispensed.

* * * * *

■ 42. Amend § 423.154 as follows:

■ a. By redesignating paragraph (a)(2) as paragraph (a)(4).

■ b. By adding paragraphs (a)(2) and (3).

■ c. By revising newly designated paragraph (a)(4).

■ d. By revising paragraph (c).

■ e. By removing paragraph (e).

■ f. By redesignating paragraph (f) as paragraph (e).

The revisions and addition read as follows:

§ 423.154 Appropriate dispensing of prescription drugs in long-term care facilities under PDPs and MA–PD plans.

(a) * * *

(2) Not penalize long-term care facilities' choice of more efficient uniform dispensing techniques described in paragraph (a)(1)(ii) of this section by prorating dispensing fees based on days' supply or quantity dispensed.

(3) Ensure that any difference in payment methodology among long-term care pharmacies incentivizes more efficient dispensing techniques.

(4) Collect and report information, in a form and manner specified by CMS, on the dispensing methodology used for each dispensing event described by paragraph (a)(1) of this section.

* * * * *

(c) *Waivers.* CMS waives the requirements under paragraph (a) of this section, except paragraphs (a)(2) and (3), for pharmacies when they service intermediate care facilities for the mentally retarded (ICFs/IID) and institutes for mental disease (IMDs) as defined in § 435.1010 and for I/T/U pharmacies (as defined in § 423.100).

* * * * *

■ 43. Amend § 423.322 by revising paragraph (b) to read as follows:

§ 423.322 Requirement for disclosure of information.

* * * * *

(b) *Restrictions on use of information.* (1) Officers, employees, and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart for the purposes of, and to the extent necessary—

(i) In carrying out this subpart, including, but not limited to, determination of payments, and payment-related oversight and program integrity activities.

(ii) In conducting oversight, evaluation, and enforcement under Title XVIII of the Act.

(2) The United States Attorney General and the Comptroller General of the United States may use the information disclosed or obtained in accordance with the provisions of this subpart for purposes of, and to the extent necessary in, carrying out health oversight activities.

(3) The restrictions described in paragraphs (b)(1) and (2) of this section do not limit either of the following:

(i) OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(ii) CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

§ 423.329 [Amended]

■ 44. Amend § 423.329(d)(1), by removing the phrase ''the amount described in § 423.782.'' and adding in its place the phrase ''the difference between the cost sharing for a non-low-income subsidy eligible beneficiary under the Part D plan and the statutory cost sharing for a low-income subsidy eligible beneficiary.''

§ 423.346 [Amended]

■ 45. Amend § 423.346(a) introductory text by removing the phrase ''as described in § 423.336)—'' and adding in its place the phrase ''as described in § 423.336) or the Coverage Gap Discount Reconciliation (as described at § 423.2320(b))—'' .

■ 46. Amend § 423.350 as follows:

■ a. In paragraph (a)(1)(iii), by removing ''; or'' and adding in its place ''.''.

■ b. In paragraph (a)(1)(iv), by removing '').'' adding in its place ''.''.

■ c. By adding paragraph (a)(1)(v).

■ d. By revising paragraph (a)(2).

■ e. By adding paragraph (b)(1)(iv).

The additions and revision read as follows:

§ 423.350 Payment appeals.

(a) * * *

(1) * * *

(v) The reconciled coverage gap discount payment under § 423.2320(b).

(2) *Payment information not subject to appeal.* Payment information submitted to CMS under § 423.322 and reconciled under § 423.343 or submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

(b) * * *

(1) * * *

(iv) For the Coverage Gap Discount Program, the date of the final reconciled payment under § 423.2320(b).

* * * * *

■ 47. Amend § 423.464 by redesignating paragraph (f)(2)(i)(B) as paragraph (f)(2)(i)(C) and adding paragraph (f)(2)(i)(B) to read as follows:

§ 423.464 Coordination of benefits with other providers of prescription drug coverage.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) Report, accept and apply benefit accumulator data in a timeframe and manner determined by CMS.

* * * * *

■ 48. Amend § 423.466 by revising the section heading and, in paragraph (b), removing the phrase ''a period not to exceed 3 years'' and adding in its place the phrase ''a period of 3 years'' to read as follows:

§ 423.466 Timeframes for coordination of benefits and claims adjustments.

* * * * *

■ 49. Amend § 423.503 by revising paragraph (a)(1) and adding paragraphs (c)(4) and (d) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits and any essential operations test.

* * * * *

(c) * * *

(4) *Nullification of approval of application.* If CMS discovers through any means that an applicant is not qualified to contract based on information gained subsequent to application approval (for example, failure of an essential operations test, absence of required employees, etc.), CMS gives the applicant written notice indicating that the approval issued under paragraph (c)(1) of this section is nullified and the applicant no longer qualifies to contract as a Part D plan sponsor.

(i) This determination is not subject to the appeals provisions in subpart N of this part.

(ii) This provision only applies to applicants that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

(d) *Withdrawal of application and bid in a previous year.* An applicant that withdraws its application and corresponding bid after the release of the low-income subsidy benchmark is not eligible to be approved as a Part D plan sponsor for the 2 succeeding annual contracting cycles.

■ 50. Amend § 423.504 by adding paragraphs (b)(10) and (d)(2)(iv) to read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(10) Pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS when neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

* * * * *

(d) * * *

(2) * * *

(iv) CMS may require that the Part D Plan sponsor hire an independent auditor to provide CMS with additional information to determine if deficiencies found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

* * * * *

■ 51. Amend § 423.505 by adding paragraphs (b)(27) and (p) to read as follows:

§ 423.505 Contact provisions.

* * * * *

(b) * * *

(27) Pass an essential operations test prior to the start of the benefit year. This provision only applies to new sponsors that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization, is offering Part D benefits during the current year.

* * * * *

(p) *Business continuity.* (1) The Part D sponsor agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations during disruptions to business operations which would

include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (p)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each Part D sponsor must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(*1*) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(*i*) Information technology (IT) systems including those supporting claims processing at point of service.

(*ii*) Provider and enrollee communication systems including telephone, Web site, and email.

(*2*) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(*1*) Employees.

(*2*) First tier, downstream, and related entities.

(*3*) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary or both.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraph (p)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (p)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every Part D sponsor must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the Part D sponsor identifies under paragraph (p)(1)(ii) of this section, for purposes of this paragraph (p)(2) of this section essential functions include at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Provision of pharmacy technical assistance.

(iv) Operation of an enrollee exceptions and appeals process including coverage determinations.

(v) Operation of call center customer services.

■ 52. Amend § 423.509 by adding paragraph (a)(4)(xii) and revising paragraph (b)(2)(i)(C) to read as follows:

§ 423.509 Termination of a contract by CMS.

(a) * * *

(4) * * *

(xii) Failure of an essential operations test before the start of the benefit year by an organization that has entered into a Part D contract with CMS when neither it, nor another subsidiary of the organization's parent organization, is offering Part D benefits during the current year.

(b) * * *

(2) * * *

(i) * * *

(C) The contract is being terminated based on the grounds specified in paragraphs (a)(4)(i) and (xii) of this section.

* * * * *

§ 423.562 [Amended]

■ 53. Amend § 423.562(a)(3) by removing the phrase ''request an exception if they disagree with the information provided by the pharmacist.'' and adding in its place the phrase ''request an exception.''.

§ 423.650 [Amended]

■ 54. Amend § 423.650 as follows:

■ a. In paragraph (a)(2), by removing the term ''under'' and adding in its place the phrase ''in accordance with''.

■ b. In paragraph (a)(4), by removing the cross-reference ''§ 423.752(a) and (b) of this part'' and adding in its place the cross-reference ''§ 423.752(a) through (b)''.

■ 55. Amend § 423.2262 by adding paragraph (a)(2) to read as follows:

§ 423.2262 Review and distribution of marketing materials.

(a) * * *

(2) If CMS does not approve or does not disapprove marketing materials within the specified review timeframe, the materials are deemed approved and the Part D sponsor may use the material.

* * * * *

§ 423.2266 [Removed and Reserved]

■ 56. Section 423.2266 is removed and reserved.

■ 57. Amend § 423.2274 by revising paragraphs (c) and (d) to read as follows:

§ 423.2274 Broker and agent requirements.

* * * * *

(c) *Annual training.* The Part D sponsor must ensure that all agents and brokers selling Medicare products are trained annually on the following:

(1) Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

(d) *Annual testing.* The Part D sponsor must ensure that all agents and brokers selling Medicare products are tested annually, to ensure the following:

(1) Appropriate knowledge and understanding of Medicare rules and regulations.

(2) Details specific to the plan products they intend to sell.

* * * * *

■ 58. Amend § 423.2320 by adding paragraph (c) to read as follows:

§ 423.2320 Payment processes for Part D sponsors.

* * * * *

(c) *Manufacturer bankruptcy.* In the event that a manufacturer declares

bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, does not pay the quarterly invoices described in § 423.2315(b)(10) used for a particular contract year's Coverage Gap Discount Reconciliation described in paragraph (b) of this section, CMS adjusts the Coverage Gap Discount Reconciliation amount of each of the affected Part D sponsors to account for the total unpaid quarterly invoiced amount owed to each of the Part D sponsors for that particular contract year being reconciled.

■ 59. Amend § 423.2325 by adding paragraph (h) to read as follows:

§ 423.2325 Provision of applicable discounts.

* * * * *

(h) *Treatment of employer group waiver plans.* As of 2014, Part D sponsors offering employer group waiver plans must provide applicable discounts to applicable beneficiaries who are employer group waiver plan enrollees as determined consistent with the defined standard benefit.

Dated: December 18, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 4, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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