Procedural Requirements

Notice and Comment

As required by the FCPIA Act, these amendments are being published as an interim final rule with an effective date of October 5, 2020. Although other notice and comment procedures are not required, OFAC invites comments on this rule related to the catch-up adjustment only. The FCPIA Act expressly exempts the inflation adjustments from the notice and comment requirements of the Administrative Procedure Act, by directing agencies to adjust CMPs for inflation ''notwithstanding section 553 of title 5, United States Code'' (Pub. L. 114–74, 129 Stat. 599; 28 U.S.C. 2461 note).

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not impose information collection requirements that would require the approval of the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects for 31 CFR Part 501

Administrative practice and procedure, Banks, banking, Blocking of assets, Enforcement guidelines, Exports, Foreign trade, Licensing, Penalties, Recordkeeping, Sanctions.

For the reasons set forth in the preamble, 31 CFR part 501 is amended as follows:

PART 501—REPORTING, PROCEDURES AND PENALTIES REGULATIONS

■ 1. The authority citation for part 501 is revised to read as follows:

Authority: 8 U.S.C. 1189; 18 U.S.C. 2332d, 2339B; 19 U.S.C. 3901–3913; 21 U.S.C. 1901–1908; 22 U.S.C. 287c, 2370(a), 6009, 6032, 7205, 8501–8551; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); 31 U.S.C. 321(b); 50 U.S.C. 1701–1706, 4301–4341.

Appendix A to Part 501—[Amended]

■ 2. In appendix A to part 501:
■ a. Amend paragraph IV.A. as follows:
■ i. Remove ''$20,000'' and in its place add ''$23,765''.
■ ii. Remove ''$50,000'' and in its place add ''$59,413''.
■ b. Amend paragraph IV.B. as follows:
■ i. Remove ''$2,500'' and add in its place ''$2,970''.
■ ii. Remove ''$5,000'' and add in its place ''$5,942''.
■ iii. Remove ''$1,000'' and add in its place ''$1,189''.
■ 5. In paragraph IV.C., remove ''$50,000'' and add in its place ''$59,522''.

Dated: August 27, 2020.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

[FR Doc. 2020–19237 Filed 9–2–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DoD–2020–HA–0050]

RIN 0720–AB82

TRICARE Coverage of Certain Medical Benefits in Response to the COVID–19 Pandemic

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Interim final rule with request for comments.

SUMMARY: The Assistant Secretary of Defense for Health Affairs (ASD(HA)) issues this interim final rule (IFR) with comment to temporarily modify the TRICARE regulation by: Waiving the three-day prior hospital qualifying stay requirement for coverage of skilled nursing facility (SNF) care; adding coverage for treatment use of investigational drugs under expanded access authorized by the United States (U.S.) Food and Drug Administration (FDA) when for the treatment of coronavirus disease 2019 (COVID–19); temporarily waiving certain provisions for acute care hospitals that will permit authorization of temporary hospital facilities and freestanding ambulatory surgical centers (ASCs) providing inpatient and outpatient hospital services; and, consistent with similar changes under the Centers for Medicaid and Medicare Services (CMS), revising diagnosis related group (DRG) reimbursement by temporarily reimbursing DRGs at a 20 percent higher rate for COVID–19 patients and temporarily waiving certain requirements for long term care hospitals (LTCHs). Finally, this IFR will also adopt Medicare's New Technology Add-On Payments (NTAPs) adjustment to DRGs for new medical services and technologies and adopt Medicare's Hospital Value Based Purchasing (HVBP) Program.

DATES:

Effective date: This interim final rule with comment is effective on September 3, 2020 through either the end of the President's national emergency (Proclamation 9994, 85 **Federal Register** (FR) 15337 (Mar. 18, 2020)) or the end of the declared public health emergency, including any extensions, (as determined by 42 United States Code (U.S.C.) 247d, except for NTAPs and HVBP, which will not expire). The ASD(HA) will publish a document announcing the expiration date. See the **SUPPLEMENTARY INFORMATION** section for more information.

Applicability date: Some policies in this IFR are applicable prior to the effective date of this IFR. The temporary waiver of the SNF three-day prior stay rule is applicable beginning March 1, 2020. The temporary DRG and LTCH reimbursement adjustments are applicable beginning January 27, 2020, and the adoption of the NTAPs and HVBP are applicable beginning January 1, 2020. All other changes are applicable on the effective date of this IFR.

Comment date: Comments are invited and must be submitted on or before November 2, 2020.

ADDRESSES: You may submit comments, identified by docket number and/or Regulation Identification Number (RIN) number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* The Department of Defense (DoD) cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Erica Ferron, Medical Benefits and Reimbursement Section, 303–676–3626, *erica.c.ferron.civ@mail.mil.*

SUPPLEMENTARY INFORMATION:

Expiration date: Unless extended after consideration of submitted comments, the medical benefit provisions in this IFR will cease to be in effect upon termination of the President's declared national emergency, in accordance with applicable law and regulation (*e.g.,* 50 U.S.C. 1622(a)), except the temporary

waiver of certain acute care hospital requirements for temporary hospitals and freestanding ASCs, which will expire when Medicare's ''Hospitals without Walls'' provision expires. The temporary reimbursement waivers under this IFR will cease to be effective upon termination of the Secretary of Health and Human Services' (HHS) Public Health Emergency (PHE), or upon other guidance, regulations, or modifications made by Medicare, in accordance with the statutory requirement that TRICARE reimburse like Medicare (10 U.S.C. 1079(i)(2)). The adoption of NTAPs and HVBP are permanent and will not expire. Because TRICARE operates both in the United States and in overseas locations, the ASD(HA), or designee, may determine that it is appropriate to continue exemptions to permanent regulation provisions for some or all of TRICARE's overseas locations serviced by the TRICARE Overseas Program contractor under 32 CFR 199.1(b) beyond termination of the President's declared national emergency based on the status of COVID–19 community spread in those locations. Such continuation of these provisions for overseas locations will be published in TRICARE's implementing instructions (TRICARE manuals), available at *http://manuals.health.mil.*

If the ASD(HA) determines it would be appropriate to make these changes permanent, the ASD(HA) will follow-up with final rulemaking. The ASD(HA) will publish a document in the **Federal Register** announcing the expiration date.

I. Executive Summary

A. Purpose of the Rule

A novel coronavirus (SARS–CoV–2), which causes COVID–19, was first detected in December 2019 and has spread rapidly throughout the world. On January 31, 2020, the Secretary of the HHS determined that a PHE had existed since January 27, 2020.[1] On March 13, 2020, the President declared a national emergency due to the COVID–19 outbreak, retroactive to March 1, 2020 (Proclamation 9994, 85 FR 15337). Following the declaration of the national emergency, the President signed into law multiple statutes to provide economic and health care relief for individuals and businesses, including health care providers. One such law was the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116–136), which in part provided for waivers of certain reimbursement provisions under Medicare.

According to World Health Organization data on May 3, 2020, there were 3,349,786 confirmed cases of COVID–19 worldwide (238,628 confirmed deaths), with 1,093,880 confirmed cases in the U.S. (62,406 confirmed deaths), with the number of cases rapidly expanding each day. Medical experts from the National Institute of Allergy and Infectious Disease anticipate more cases in the U.S. and overseas in the coming months.[2]

In light of the rapid spread of COVID–19, the Centers for Disease Control and Prevention has urged Americans to work and engage in schooling from home whenever possible as well as to avoid congregating in groups. Many States (*e.g.,* Washington, New York) and cities (*e.g.,* Los Angeles) imposed stay-at-home orders during the early months of the pandemic, closing all but essential businesses such as medical care and grocery stores, all to prevent further spread of the disease.

While stay-at-home orders and recommendations for social distancing have slowed the spread of COVID–19, there is currently no cure, nor are there any FDA approved vaccines indicated for the prevention of COVID–19. It is likely that the health care system, in the U.S. and abroad, will need to contend with this threat for months, if not years. Many COVID–19 treatments are being tried, including convalescent plasma from patients recovered from COVID–19 and new potential antiviral drugs.

A TRICARE COVID–19-related IFR published on May 12, 2020 (85 FR 27921), provides a temporary exception to the regulatory exclusion prohibiting audio-only telehealth services, temporarily eliminates copayments and cost-shares for TRICARE Prime and Select beneficiaries utilizing authorized telehealth services provided by network providers as a necessary incentive to prevent further spread of COVID–19, and temporarily authorizes reimbursement of interstate practice by providers (both in-person and remotely) for care provided to TRICARE beneficiaries when such practice is permitted by federal or state law, even if the provider is not licensed in the state where practicing. That IFR was focused on temporary changes to the TRICARE program to aid in slowing community transmission of COVID–19. This second IFR continues efforts by the ASD(HA) to implement temporary regulation changes in response to COVID–19 by focusing on temporary benefit and reimbursement changes that will support treatment of TRICARE beneficiaries. It also implements two permanent regulation changes consistent with the statutory requirement that TRICARE reimburse like Medicare, to the extent practicable.

Pursuant to the President's national emergency declaration and as a result of the worldwide COVID–19 pandemic, the ASD(HA) hereby modifies the following regulations, but in each case, only to the extent determined necessary to ensure that TRICARE beneficiaries have access to the most up-to-date care required for the diagnosis and treatment of COVID–19, and that TRICARE continues to reimburse like Medicare, to the extent practicable, as required by statute. The following regulations are temporarily modified (except NTAPs and HVBP, which are permanently modified):

a. 32 CFR 199.4(b)(3)(xiv): As required by law, 10 U.S.C. 1074j(b)(1), the TRICARE skilled nursing facility (SNF) benefit is provided in the manner and under the conditions established for the Medicare SNF benefit. Consistent with Medicare, then, TRICARE's regulation adopted Medicare's requirement that an individual was an inpatient of a hospital for not less than 3 consecutive calendar days before his discharge from the hospital (three-day prior hospital stay), for coverage of a SNF admission. Medicare, under its authority granted by Sections 1812(f) of the Social Security Act, has waived this requirement during the COVID–19 pandemic. As required by the TRICARE statute for the SNF benefit to mirror that of Medicare, this provision of the IFR temporarily waives the regulatory requirement for a three-day prior hospital stay for TRICARE beneficiaries, providing temporary emergency coverage for those beneficiaries who need to be transferred during the period of the COVID–19 pandemic. This temporary waiver is in effect for the duration of the President's national emergency for the COVID–19 outbreak, retroactive to March 1, 2020.

b. 32 CFR 199.4(g)(15): This change temporarily adds coverage for the use of investigational drugs for the treatment of COVID–19 under FDA's expanded access provision at 21 CFR 312, subpart I. Under this provision, TRICARE coverage of investigational drugs provided under expanded access will include both costs associated with administration of the investigational drug, as well as the cost of the investigational drug itself when the investigational drug is for the treatment

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] *https://www.niaid.nih.gov/news-events/covid-19-reminder-challenge-emerging-infectious-diseases.*

of COVID–19. This will include investigational drugs and associated costs provided for treatment of patients under expanded access INDs and protocols s authorized by the FDA, but will not include use of investigational drugs in clinical trials. The temporary modification under paragraph 199.4(g)(15)(i)(A) is effective for the period of the President's national emergency for the COVID–19 outbreak, and will only apply to treatments for COVID–19. However, we plan to re-evaluate our current exclusion preventing coverage of investigational drugs provided for treatment use under expanded access and may make permanent revisions to the regulation, if appropriate, after a thorough evaluation of the costs, benefits, risks, and other considerations. We invite comment on the temporary coverage of investigational drugs provided under expanded access for the treatment of COVID–19, as well as potential future coverage of investigational drugs for treatment use under expanded access for individuals with serious or life-threatening diseases (not including clinical trials not otherwise covered by TRICARE) for potential inclusion in a future final rule.

c. 32 CFR 199.6(b)(4)(i): This change will temporarily exempt certain temporary hospital facilities and locations, and freestanding ASCs that enroll as hospitals with Medicare from the institutional provider requirements for acute care hospitals in 32 CFR 199.6(b)(4)(i), but only to the extent that such exemptions are required to ensure adequate beneficiary access to acute care facilities during the COVID–19 national emergency. Under current regulatory requirements, temporary hospital facilities (to include hospitals that are already TRICARE-authorized providers operating in a temporary location, such as a parking lot, or at a temporary facility, such as a repurposed convention center or an erected tent) and freestanding ASCs which provide inpatient and outpatient hospital services are not TRICARE-authorized providers because they do not meet the institutional provider requirements for hospitals. This temporary waiver of institutional requirements is consistent with Medicare's ''Hospitals without Walls'' initiative. It also is consistent with the statutory requirement at 10 U.S.C. 1079(i)(2), which establishes that the amount paid to hospitals and other institutional providers is in accordance with the same reimbursement methodology as apply to payments to providers of services of the same type under Medicare, when practicable. This temporary change is in effect for the duration of Medicare's ''Hospitals without Walls'' initiative for COVID–19.

d. 32 CFR 199.14(a)(1)(iii)(E): Adjustments to the DRG-based reimbursement amounts. TRICARE shall reimburse acute care hospitals a 20 percent increase of the DRG for an individual diagnosed with COVID–19, confirmed through documentation of a positive COVID–19 laboratory test in the patient's medical record, discharged during the COVID–19 PHE period, retroactive to January 27, 2020. Further, TRICARE shall permanently adopt (1) Medicare's NTAP payment adjustment to DRGs, for new technologies approved by Medicare, and (2) Medicare's HVBP Program. These changes are in accordance with the statutory requirement that TRICARE inpatient care ''payments shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under Medicare.'' The ASD(HA) has determined that it is practicable to adopt this Medicare adjustment to the TRICARE DRG-based reimbursement amounts.

e. 32 CFR 199.14(a)(9): Reimbursement for inpatient services provided by a LTCH. By statute, 10 U.S.C. 1079(i)(2), TRICARE shall, to the extent practicable, reimburse institutional providers in accordance with Medicare reimbursement rules. As such, TRICARE has generally adopted the Medicare inpatient prospective payment system for LTCHs (32 CFR 199.14(a)(9)), including Medicare's site neutral payment provisions (adopted December 29, 2017). Section 3711 of the CARES Act directs Medicare to waive the site neutral payment provisions for LTCHs during the COVID–19 PHE period. The ASD(HA) has determined that it is practicable to temporarily adopt this Medicare LTCH reimbursement waiver of the site neutral payment provisions for LTCHs for a discharge if the admission occurs during the COVID–19 PHE, retroactive to January 27, 2020, and is in response to the COVID–19 PHE. The effective and expiration dates are consistent with Medicare's dates for their temporary waiver of LTCH site neutral payment provisions in response to COVID–19, as required by the statutory mandate that TRICARE reimburse like Medicare, where practicable.

f. Dates. These modifications will become effective on September 3, 2020, and will cease to be in effect upon termination of the President's declared national emergency, except as otherwise noted in this paragraph. The NTAPs and HVBP provisions are applicable beginning January 1, 2020, and will not expire. The SNF three-day prior stay waiver is applicable beginning March 1, 2020. The temporary hospital and freestanding ASC acute care hospital requirements waiver expires upon expiration of Medicare's ''Hospitals without Walls'' initiative. The temporary reimbursement changes (20 percent increased DRG for COVID–19 patients and LTCH changes) are applicable beginning January 27, 2020, and will cease to be in effect upon termination of the HHS Secretary's PHE. The Secretary of HHS used his authority in the Public Health Service Act to declare a PHE in the entire United States on January 31, 2020, effective January 27, 2020. Since Medicare's applicable period for the PHE began on January 27, 2020, TRICARE will also begin the applicable period for the PHE on January 27, 2020, for the increase of the DRG by 20 percent for COVID–19 discharges and for waiver of site neutral payment provisions for LTCHs with admissions occurring during the COVID–19 PHE and in response to the PHE. With TRICARE beneficiaries located worldwide, the ASD(HA), or designee, may allow the provisions of this IFR to continue after termination of the President's national emergency for some or all of TRICARE's overseas locations based on the status of COVID–19 community transmission in those locations. Such continuation of these provisions for overseas locations will be published in TRICARE's implementing instructions (TRICARE manuals), available at *http://manuals.health.mil.*

Certain provisions of this IFR may be made permanent while others are anticipated to be removed when the COVID–19 pandemic has concluded. The DoD may issue a final rule to make permanent changes.

B. Interim Final Rule Justification

Agency rulemaking is governed by section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* Section 553(b) requires that, unless the rule falls within one of the enumerated exemptions, the DoD must publish a notice of proposed rulemaking in the **Federal Register** that provides interested persons an opportunity to submit written data, views, or arguments, prior to finalization of regulatory requirements. Section 553(b)(B) of the APA authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement when the agency, for ''good cause,'' finds that notice and public comment thereon are impracticable, unnecessary, or contrary

to the public interest. Section 553(d)(3) requires that an agency must include an explanation of such good cause with the publication of the new rule.

As noted in this preamble, the U.S., as well as numerous other countries, have taken unprecedented measures to try to contain or slow the spread of COVID–19. While studies of potential treatments of COVID–19 are in progress, these studies are expected to take time. Unfortunately, TRICARE beneficiaries infected with COVID–19 may not have time to wait for these treatments, given the rapidity with which the disease overtakes infected individuals who develop the most severe responses to the illness. Additionally, hospital resources being flexed to respond to COVID–19 cannot wait for the reimbursement relief offered in this IFR.

Given the national emergency caused by COVID–19, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay these implementing regulations until a full public notice-and-comment process is completed.

Additional good cause exists to publish as an IFR the permanent amendments to the TRICARE regulation regarding adoption of the Medicare DRG adjustments for NTAP and the HVBP Program. As previously noted, TRICARE is mandated by law, 10 U.S.C. 1079(i)(2), to reimburse institutional providers using the Medicare reimbursement methodologies, to the extent practicable. Also, TRICARE is required by section 705(a) of the National Defense Authorization Act (NDAA) to implement a value-based incentive program to encourage health care providers to improve the quality and delivery of services to TRICARE beneficiaries. The ASD(HA) is authorized by the Act to adopt value-based programs created by the CMS. As such, the ASD(HA) has determined that it is practicable to adopt as TRICARE DRG-based reimbursement adjustments, the Medicare NTAP and HVBP Program adjustments which Medicare has implemented through formal rule-making. In exercising his discretionary authority under statute, the ASD(HA) has determined that the purpose for prior notice and public comment has been satisfied by the Medicare rule-making and that good cause exists to avoid delay as further notice and public comment would be impracticable, unnecessary, or contrary to the public interest. Nonetheless, public comments on this IFR are invited and DoD is committed to considering all comments and issuing a final rule as soon as practicable.

Therefore, pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated in this preamble, the ASD(HA), concludes that there is good cause to dispense with prior public notice and the opportunity to comment on this rule before finalizing this rule. For the same reasons, the ASD(HA) has determined, consistent with section 553(d) of the APA, that there is good cause to make this IFR effective immediately upon publication in the FR, with applicability of its provisions to coincide with the President's national emergency for the COVID–19 outbreak or the HHS Secretary's PHE, as stated in this rule.

C. Summary of Major Provisions

a. Changes to the TRICARE Benefit

SNF Three-Day Prior Hospital Waiver

This provision, 32 CFR 199.4(b)(3)(xiv), temporarily waives the requirement that an individual was an inpatient of a hospital for not less than 3 consecutive calendar days before his discharge from the hospital (three-day prior hospital stay), for coverage of a SNF admission, for those beneficiaries who need to be transferred as a result of the effect of the COVID–19 pandemic. This will align TRICARE's benefit with Medicare's for SNF admission as required by 10 U.S.C. 1074j(b), as Medicare has waived its three-day prior hospital stay requirement during the COVID–19 pandemic.

Investigational Drugs Provided Under Expanded Access for the Treatment of COVID–19

This provision, 32 CFR 199.4(g)(15)(i)(A), temporarily modifies TRICARE regulations for coverage of investigational drugs provided for treatment use under expanded access authorized by the FDA in a patient who is seriously ill or has a life threatening condition. Title 10 U.S.C. 1079(a)(12) mandates care provided to TRICARE beneficiaries to be medically or psychologically necessary, unless that care is provided by a Christian Science practitioner or in a National Institute of Health clinical trial when there is an agreement with HHS.

The existing regulations on treatment use of investigational drugs were first implemented in 1996 (62 FR 625), in a final rule that codified TRICARE procedures for determining when care provided to TRICARE beneficiaries is medically necessary under the statute. The regulations, minus minor revisions to the definition of off-label drugs and devices and removal of a list of unproven treatments, are unchanged from their establishment almost twenty-five years ago. The regulations currently allow for coverage of care associated with treatment investigational new drugs (INDs), but do not permit coverage of the treatment IND itself because a treatment IND is not labeled for commercial marketing in the U.S. Treatment INDs are one type of treatment use of investigational drugs under expanded access and are the only type mentioned in the regulation.

While we were considering potential temporary regulatory changes required in response to COVID–19, we found it appropriate to reconsider coverage of treatment INDs, and, in doing so, opted to expand our consideration to the larger universe of investigational drugs provided for treatment use under expanded access. FDA's regulations on expanded access of investigational drugs for treatment use are provided at 21 CFR, subpart I. Generally, drugs provided for treatment use under expanded access have not yet been approved for commercial marketing by the FDA. In these cases, a drug being studied in clinical trials might be used for treatment outside of such trials for patients for which there is no alternative. The FDA permits treatment use of an investigational drug under expanded access when the drug would treat a serious or life-threatening illness when there is no comparable or satisfactory alternative, the potential patient benefit justifies the potential risks of the treatment use, and providing the investigational drug will not compromise the potential development or interfere with the clinical investigations that could support marketing approval of the investigational drug for the expanded access use. Treatment use with an investigational drug under expanded access is subject to the requirements for informed consent and institutional review board review and approval.

Under this temporary provision, we will, for the first time, cover not just the care associated with administration of an investigational drug, but the investigational drug itself, when the investigational drug is for the treatment of COVID–19 or its associated sequelae. This use may be authorized in any setting for which the FDA allows treatment use of an investigational drug under expanded access to proceed. As an example, convalescent plasma, an investigational product, is the donated plasma from a person who has recovered from COVID–19, which is administered to a COVID–19 patient under the hypothesis that antibodies will aid the ill person in fighting the disease. Convalescent plasma has not yet been approved by the FDA for use in treating COVID–19, but is currently

available for administering or studying through clinical trials or expanded access. Expanded access allows for treatment of patients with serious or life-threatening symptoms of COVID–19 but who are unable to participate in clinical trials. Treatment use of an investigational drug under expanded access is being offered on a case-by-case basis as an emergency individual treatment, and on a larger scale in participating acute care facilities where authorization has already been given to the facility prior to need by the individual patient, essentially speeding access to the treatment. Allowing TRICARE beneficiaries access to investigational drugs for serious and life-threatening COVID–19 conditions under expanded access is essential given the rapid progression of the disease and the lack of FDA-approved alternatives. We note, however, that if a manufacturer, provider, or supplier does not charge other payers, including other Federal payers, then billing TRICARE for an investigational drug may constitute inappropriate billing practices under § 199.9 of this regulation. In other words, if a drug manufacturer makes an investigational drug available for treatment use under expanded access at reduced or no cost to non-TRICARE patients, they are expected to provide the investigational drug to TRICARE patients at the same reduced or no-cost.

For beneficiaries overseas, TRICARE has long had a policy exemption for non-FDA-approved drugs due to differences in the way prescription drugs are managed outside of the United States. When implementing this temporary regulation change, the DHA intends to permit coverage of similar investigational drugs for treatment use overseas when the criteria are substantially similar to the use of investigational drugs for treatment use under expanded access in the U.S. That is, the drug is intended to treat a serious or life-threatening case of COVID–19 or its sequelae when there is no satisfactory or comparable alternative, the potential patient benefit justifies the potential risks of the treatment use, and providing the investigational drug will not compromise the potential development or interfere with the clinical investigations that could support marketing approval of the investigational drug for the expanded access use.

The change under this provision is temporary for the duration of the President's national emergency for the COVID–19 outbreak. An investigational drug provided for treatment use under expanded access under the requirements of this provision may continue to be covered beyond the national emergency if the course of treatment was started prior to the end of the national emergency. We intend to use this national emergency period to re-evaluate our current exclusion on coverage of treatment INDs and may revise the regulation to cover investigational drugs for treatment use under expanded access for all indications if appropriate after a thorough evaluation of the costs, benefits, risks, and other considerations. We invite public comment on this provision.

Temporary Hospital Facilities and Freestanding ASCs Temporarily Enrolling as Hospitals

Due to the lack of hospital capacity and the strain on resources such as hospital beds as a result of the COVID–19 pandemic, state governments, existing hospitals, and other entities have begun constructing temporary hospital facilities (also known as temporary expansion sites and alternate care sites) to (1) treat patients recovering from COVID–19; and (2) treat patients with other conditions in order to mitigate their exposure to COVID–19. These temporary hospital facilities are typically operated by the U.S. Armed Forces, local or state governments, or existing hospital systems using HHS and the Army Corps of Engineers guidance on the establishment, operationalization, and management of alternate care sites. Additionally, ASCs have begun performing services typically provided in inpatient hospital settings to protect patients from exposure to COVID–19 and to reduce the strain on hospital resources.

As part of their IFR with Comment published April 6, 2020 (85 FR 19230), CMS announced their ''Hospitals without Walls'' initiative, through which CMS will permit Medicare coverage for services and supplies provided in temporary hospital locations and facilities, and allow freestanding ASCs to enroll as hospitals and provide inpatient and outpatient hospital services. Specifically, CMS is waiving requirements under the Medicare conditions of participation related to physical environment (42 CFR 482.41) and physical plant and environment (42 CFR 485.623), and the provider-based department requirements at 42 CFR 413.65. Under these waivers, Medicare is requiring that ASCs enroll as hospitals and that temporary hospital facilities meet the hospital conditions of participation in effect during the COVID–19 PHE. Temporary hospital facilities include (1) a hospital providing services at a location other than the hospital's physical structure (*e.g.,* the hospital parking lot) and (2) when a hospital is handling the majority of the operations of an alternate care site (*e.g.,* a hospital set up in a convention center).

While there are no direct corollaries in TRICARE regulation to those requirements being waived under Medicare, there do exist in TRICARE regulation certain requirements that would prevent similarly authorizing temporary hospitals and allowing freestanding ASCs to be considered as hospitals for the purposes of payment. 32 CFR 199.6(b)(4)(i) lists the requirements for providers to be considered TRICARE-authorized acute care hospital providers. It may not be possible for many temporary hospital facilities to meet all of these requirements, such as having Joint Commission (previously known as the Joint Commission on Accreditation of Hospitals) accreditation status or surveying of new facilities. Additionally, freestanding ASCs that are already TRICARE-authorized providers cannot register as hospitals because, at a minimum, they do not meet the requirement of primarily providing services to inpatients and they may not meet certain other requirements such as Joint Commission accreditation. While we assert that these institutional requirements continue to be necessary for acute care hospitals, we also recognize that during the national emergency for the COVID–19 outbreak, it may be necessary to relax some of these requirements so that beneficiaries can be assured of access to acute care settings. Unlike Medicare, TRICARE lacks the authority to waive individual regulatory requirements for any type of provider without rulemaking. Therefore, this provision will temporarily waive the acute care hospital institutional provider requirements in 32 CFR 199.6(b)(4)(i) for temporary hospital facilities and freestanding ASCs that enroll as hospitals with Medicare, but only to the extent necessary to ensure that TRICARE beneficiaries receive adequate access to acute inpatient care during the COVID–19 pandemic. The Director of the Defense Health Agency (DHA), may establish further requirements for such facilities in the implementing instructions (as found in the TRICARE manuals).

Our intent is to adopt certain requirements related to Medicare's ''Hospitals without Walls'' waiver to allow hospital services to be provided in temporary hospital facilities for the duration of the President's national emergency for the COVID–19 outbreak.

Although there is no requirement to adopt Medicare's condition of participation requirements for hospitals, this provision does support the statutory directive in 10 U.S.C. 1079(i)(2) to pay like Medicare, when practicable. Title 10 U.S.C. 1079(i)(2) establishes that the amount paid to hospitals and other institutional providers is in accordance with the same reimbursement methodology, to the extent practicable, as apply to payments to providers of services of the same type under Medicare. Under this provision, hospitals that are already TRICARE-authorized providers and are operating in a manner consistent with their state's emergency plan in effect during the COVID–19 Presidential national emergency, will be reimbursed for covered inpatient and outpatient services using the same methodologies as if those services were provided at their permanent locations. Freestanding ASCs that enroll with Medicare as a hospital can also change their ASC status to a hospital under TRICARE. This means that, depending on the type of service provided, TRICARE's DRG System or Outpatient Prospective Payment System will be used for reimbursement. If a freestanding ASC initially enrolls as a hospital, but later changes their enrollment status back to an ASC, or if Medicare terminates the ASC's hospital status, then TRICARE will no longer recognize that ASC as being a hospital, effective the date of the enrollment status changes. If Medicare alters its requirements for coverage of temporary hospitals or freestanding ASCs acting as hospitals, the Director of DHA, or designee, will evaluate those changes and adopt, when practicable, in the implementing instructions.

These changes align with Medicare's ''Hospitals without Walls'' initiative. While we are waiving the institutional provider requirements under paragraph 199.6(b)(4)(i), we are still requiring that temporary hospital facilities and freestanding ASCs meet Medicare's conditions of participation established for this Presidential national emergency, which coincide with many of TRICARE's requirements for hospitals, such as operational, staffing, and supervisory requirements. This change will also improve the access of beneficiaries to medically necessary care provided in temporary hospital facilities and freestanding ASCs and may improve outcomes for beneficiaries by allowing them to receive treatment in facilities that are being used to prevent the spread of COVID–19 to COVID–19-negative patients and to mitigate hospitals' lack of capacity and shortages of resources. This change is temporary for the duration of Medicare's ''Hospitals without Walls'' initiative.

b. Reimbursement Modifications Consistent With Medicare Requirements

Adjustments to DRG-Based Payment Amounts

This IFR implements three changes to DRG-based payment amounts. By statute, 10 U.S.C. 1079(i)(2), TRICARE shall, to the extent practicable, reimburse institutional providers in accordance with Medicare reimbursement rules. As such, TRICARE has generally adopted the Medicare inpatient prospective payment system (DRG; *e.g.,* see 32 CFR 199.14(a)(1)). The first DRG-based payment modification is a result of Section 3710 of the CARES Act, which directed Medicare to increase the weighting factor of the assigned DRG by 20 percent for an individual diagnosed with COVID–19 discharged during the COVID–19 PHE period. The ASD(HA) has determined that it is practicable to adopt this Medicare DRG adjustment and issues this IFR to adopt Medicare's increase of the DRG by 20 percent for an individual diagnosed with COVID–19 discharged during the COVID–19 PHE period, retroactive to January 27, 2020.

The second DRG-based payment modification in this IFR permanently adopts Medicare's NTAPs. The Benefits and Improvement Protection Act of 2000 mandated CMS to establish a process of identifying and ensuring adequate payment for new medical services and technologies under Medicare. In CMS' September 7, 2001, final rule (66 FR 46902), Medicare established a methodology to provide hospitals with a new type of outlier payment for new medical services and technologies furnished to Medicare beneficiaries. CMS implemented the NTAPs in Fiscal Year (FY) 2003.

While it may have been practicable for TRICARE to adopt CMS' NTAPs when enacted, there was no means to allow coverage for these emerging technologies. Coverage of a particular new technology under Medicare does not guarantee coverage under TRICARE. The TRICARE benefit is covered by a separate set of statutes and while benefits under the two programs are similar, they are not identical. Initially, these emerging technologies would not have met the coverage criteria under TRICARE's hierarchy of reliable evidence, so the NTAP was not adopted. Over time, though, Medicare's NTAP provision has added items permitted by TRICARE (*e.g.,* orphan drugs for rare diseases). Since all current NTAPs are permitted by TRICARE, and any future NTAPs are required to be a TRICARE benefit, we find it appropriate to adopt Medicare's NTAP provision now, in order to ensure this payment methodology is available for TRICARE beneficiaries.

When TRICARE covers emerging technology as a benefit under existing statute and regulation, the DHA will adopt the new technologies DRG add-on payment. DHA further adopts CMS' NTAP methodology as specified in 42 CFR 412.87 and 412.88. DHA will follow CMS' effective date for NTAPs (*i.e.,* currently the FY begin date), and will adopt any changes to the Medicare effective date in the future. Medicare typically provides NTAPs for two to three years (depending on when the technology receives FDA marketing authorization). This provision is effective from January 1, 2020, and we will issue a final rule to permanently allow NTAPs in the future.

We invite public comment on all parts of this provision of the IFR, including permanent adoption of NTAPs. We feel that since Medicare has already published a final rule for the NTAP and collected public comment, it is appropriate for TRICARE to adopt under this IFR. The ASD(HA) has determined that it is practicable to adopt this Medicare DRG adjustment and issues this IFR to adopt Medicare's NTAP for otherwise authorized TRICARE services and supplies.

The final DRG-based payment modification in this IFR permanently adopts Medicare's HVBP program. Section 705(a) of the NDAA for FY 2017 authorizes the development and implementation of value-based incentive programs to encourage health care providers to improve the quality and delivery of services to Medicare beneficiaries. The statute further allows the Secretary to adopt value-based incentive programs conducted by CMS or any other federal government, state government, or commercial health care program in fulfillment of the statutory authority granted under this section.

Congress authorized the Medicare Inpatient HVBP in Section 3001(a) of the Patient Protection and Affordable Care Act. The program uses the hospital quality data reporting infrastructure that was developed for the Hospital Inpatient Quality Reporting Program, authorized by Section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Medicare HVBP program provides incentives to hospitals that show improvement in areas of health care delivery, process improvement, and increased patient satisfaction. The

program is budget-neutral with a two percent reduction in hospitals' base payments being redistributed by Medicare to hospitals in the form of incentive payments based on the hospital's Total Performance Score.

Per 10 U.S.C. 1079(i)(2), the amount to be paid to hospitals, SNFs, and other institutional providers under TRICARE shall, by statute, be established ''to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under Medicare.'' This IFR adopts Medicare's HBVP program for TRICARE, in accordance with this statutory requirement and encouragement by Congress to adopt value-based payment mechanisms.

TRICARE will continue to use its current method of calculating hospital DRG weights and rates. Medicare hospital payment adjustments would be obtained and applied from the CMS website by the Managed Care Support Contractors. The Medicare provider identification number will then be used to match the HVBP adjustments to the correct claim and apply the adjustment factor to each TRICARE discharge. Adopting Medicare's HVBP program approach would not require any additional reporting from TRICARE hospitals, as they are currently participating in the Medicare HVBP program. DHA will adopt the HVBP adjustment. DHA further adopts CMS' HVBP program and methodology. This provision is applicable from January 1, 2020, and we will issue a final rule to permanently allow Medicare's HVBP adjustments in the future.

We invite public comment on all parts of this provision of the IFR, including permanent adoption of HVBP. We feel that since Medicare has already published a final rule for the HVBP and collected public comment, it is appropriate for TRICARE to adopt under this IFR. The ASD(HA) has determined that it is practicable to adopt this Medicare DRG adjustment and issues this IFR to adopt Medicare's HVBP Program.

Reimbursement for Inpatient Services Provided by LTCHs

Title 32 CFR 199.14(a)(9) Reimbursement for inpatient services provided by an LTCH. TRICARE shall reimburse all LTCH cases with an admission date occurring on or after January 27, 2020, and admitted during the COVID–19 PHE period, the LTCH PPS standard Federal rate for claims. This is in accordance with the statutory requirement that TRICARE inpatient care ''payments shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under Medicare.''

D. Legal Authority for This Program

This rule is issued under 10 U.S.C. 1073(a)(2) giving authority and responsibility to the Secretary of Defense to administer the TRICARE program. The text of 10 U.S.C. chapter 55 can be found at *https://manuals.health.mil/.*

II. Regulatory History

Each of the sections being modified by this rule are revised every few years to ensure requirements continue to align with the evolving health care field. Title 32 CFR 199.4 was most recently updated on September 29, 2017, with an IFR (82 FR 45438) that implemented the Congressionally-mandated TRICARE Select benefit plan. Its revision to 32 CFR 199.4 included the addition of medically necessary foods as a benefit under the TRICARE Basic Program. Two paragraphs within § 199.4 are being modified by this IFR.

Paragraph 199.4(b)(3)(xiv) was originally created on June 13, 2002 (67 FR 40602), as part of an IFR partially implementing the TRICARE ''sub-acute and long-term care program reform'' enacted by Congress in the National Defense Authorization Act for Fiscal Year 2002, which created 10 U.S.C. 1074j, Sub-Acute Care Program. TRICARE covered SNF care prior to this change, but the NDAA required TRICARE to model its SNF program on Medicare's, with the exception of Medicare's day limits. The regulation adopted Medicare's prospective payment method and most of its benefit structure for SNF care, including Medicare's three-day prior stay rule. Prior to this change, TRICARE did not have a three-day prior stay rule. Paragraph 199.4(b)(3)(xiv) has not been revised since its enactment.

The provisions of paragraph 199.4(g)(15) were last revised on June 27, 2012 (77 FR 38177), with a clarification of the definition of off-label coverage of drugs and devices, and the removal a partial list of unproven drugs, devices, and medical treatments or procedures. The partial list of unproven treatments was eliminated due to rapid and extensive changes in medical technology that made it infeasible to maintain the list through updates to the regulation. The final rule stated unproven treatments would continue to be listed in the TRICARE manuals.

Title 32 CFR 199.6 was last revised on March 17, 2020 (85 FR 15061); the change added licensed or certified physical therapist assistants and occupational therapy assistants as TRICARE-authorized providers. Paragraph 199.6(b)(4)(i) with requirements for acute care hospitals is a long-standing component of the TRICARE program that has not been revised for over 20 years.

Title 32 CFR 199.14 was last revised on February 15, 2019 (84 FR 4333), as part of the final rule implementing the TRICARE Select benefit program. The revision to § 199.14 delayed the effective date for updates to the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) DRG-based payment system based on Medicare's Prospective Payment System to January 1 of each year, the start date for the program year under TRICARE Select. Two paragraphs within § 199.14 are modified by this IFR.

The first, paragraph 199.14(a)(1)(iii)(E), was last substantially revised with a final rule published on September 10, 1998 (63 FR 48446). Due to an error in the final rule, the changes were not formalized until a technical revision was published via a final rule correction issued on November 8, 1999 (64 FR 60671). This change updated numerous portions of § 199.14 to more closely align TRICARE reimbursement with Medicare's. This rule revised paragraph 199.14(a)(1)(iii)(E) regarding calculation of the indirect medical education adjustment factor, as well as the calculation of cost outlier payments for children's hospitals.

The second, paragraph 199.14(a)(9), was most recently modified on December 29, 2017 (82 FR 61692), as part of a final rule establishing reimbursement rates for LTCHs in accordance with the requirement that TRICARE reimburse like Medicare for services of the same type. Prior to that, TRICARE covered care in LTCHs but did not follow Medicare's DRG, instead reimbursing billed charges or network discount.

III. Regulatory Analysis

A. Regulatory Planning and Review

a. Executive Orders

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Accordingly, the rule has been reviewed by the Office of Management and Budget under the requirements of these Executive Orders. This rule has been designated a ''significant regulatory action'' although, not determined to be economically significant, under section 3(f) of Executive Order 12866.

b. Summary

The modifications to paragraph 199.4(b)(3)(xiv) in this IFR will temporarily waive the requirement that an individual was an inpatient of a hospital for not less than 3 consecutive calendar days before his discharge from the hospital (three-day prior hospital stay), for coverage of a SNF admission for those beneficiaries who need to be transferred as a result of the effect of COVID–19.

The modification to paragraph 199.4(g)(15)(i)(A) in this IFR will temporarily allow changes to the TRICARE benefit by authorizing cost-sharing of investigational drugs for the treatment of COVID–19 and its sequelae under expanded access. This will expand existing coverage, which only permits coverage of care associated with administration of a treatment IND, but not the investigational drug itself. This coverage will be authorized for treatment use of an investigational drug under expanded access but not in clinical trials.

The modifications to paragraph 199.6(b)(4)(i) in this IFR will temporarily exempt temporary hospital facilities and freestanding ASCs that enroll as hospitals with Medicare from the institutional provider requirements for acute care hospitals described in paragraph 199.6(b)(4)(i). This will allow these facilities to provide inpatient and outpatient hospital services to improve the access of beneficiaries to medically necessary care. This change is also consistent with 10 U.S.C. 1079(i)(2) to reimburse hospitals and other institutional providers in accordance with the same reimbursement methodology as Medicare, when practicable.

The modifications to paragraph 199.14(a)(1)(iii)(E) in this IFR will temporarily adopt the Medicare Hospital Inpatient Prospective Payment Add-On Payment for COVID–19 patients during the COVID–19 PHE period, permanently adopt Medicare's NTAP payment and HVBP Program. The add-on payment for COVID–19 patients increases the weighting factor that would otherwise apply to the DRG to which the discharge is assigned, by 20 percent. The NTAP allows for an additional payment in addition to the DRG payment, for new and emerging technologies approved by Medicare. The HVBP Program provides incentives to hospitals that show improvement in areas of health care delivery, process improvement, and increased patient satisfaction.

The modifications to paragraph 199.14(a)(9)(i) in this IFR will adopt the Medicare waiver of site neutral payment provisions for LTCHs during the COVID–19 PHE period. This modification waives the site neutral payment provisions, and reimburses all LTCH cases at the LTCH PPS standard Federal rate for claims within the COVID–19 PHE period.

c. Affected Population

This change impacts all TRICARE beneficiaries who have a serious or life threatening case of COVID–19 and would benefit from treatment with an investigational drug under expanded access. TRICARE-authorized providers will be impacted by being able to treat those patients receiving an investigational drug for treatment use under expanded access. SNFs, LTCHs, and inpatient hospital care providers will be impacted by receiving reimbursement consistent with Medicare's reimbursement both for COVID–19 patients and under the NTAP and HVBP payment provisions. TRICARE's health care contractors will be impacted by being required to implement the provisions of this regulatory change. State, local, and tribal governments will not be impacted.

d. Costs

The cost estimates related to the changes discussed in this IFR include incremental health care cost increases as well as administrative costs to the government. The duration of the COVID–19 national emergency and HHS PHE are uncertain, resulting in a range of estimates for each provision in this IFR. Cost estimates are provided for an approximate nine-month (ending 12/31/2020) and eighteen-month scenario (ending 9/30/2021). The nine-month and 18-month periods would be longer for those provisions applicable beginning in January of this year, and shorter for those effective the date this IFR publishes. The terms nine-month and 18-month period are used throughout this estimate for the sake of simplicity.

The cost estimates consider whether the outbreak will have more than one active stage. The first active stage is considered to be March through August 2020, based on the Institutes for Health Metrics and Evaluation data as of May 27, 2020.[3] A two-wave scenario would have a second stage in winter/spring 2021, while a three-wave scenario would have additional waves from September 2020 to December 2020 and from January 2021 to June 2021.

Based on these factors, we estimate that the total cost estimate for this IFR will be between $43.6M and $59.4M for a nine-month period, and $66.3M to $82.1M for an 18-month period. This estimate includes just over $1M in administrative start-up costs and no ongoing administrative costs. The primary cost drivers in this analysis are the reimbursement changes being adopted under the statutory requirement that TRICARE reimburse like Medicare; that is, the 20 percent DRG increase for COVID–19 patients, the adoption of NTAPs and HVBP, and the waiver of LTCH site neutral payment reductions.

A breakdown of costs, by provision, is provided in the below table. A discussion of assumptions follows.

Provision	Nine-month scenario (M)	Eighteen-month scenario (M)
Paragraph 199.4(b)(3)(xiv)—SNF Three-Day Prior Stay Waiver	$0.3	$0.6
Paragraph 199.4(g)(15)(A)—Investigational Drugs under Expanded Access for COVID–19	0.7–2.2	2.7–4.2
Paragraph 199.6(b)(4)(i)—Temporary Hospitals and Freestanding ASCs Registering as Hospitals	0	0
Paragraph 199.14(a)(1)(iii)(E)(2)—20 Percent DRG Increase for COVID–19 Patients	27.7–42	37.1–51.4
Paragraph 199.14(a)(1)(iii)(E)(5)—NTAPs	5.7	11.6

[3] *https://covid19.healthdata.org/united-states-of-america.*

Provision	Nine-month scenario (M)	Eighteen-month scenario (M)
Paragraph 199.14(a)(1)(iii)(E)(6)—HVBP	2.5	2.5
Paragraph 199.14(a)(9)—LTCH Site Neutral Payments	5.6	10.6
Administrative Costs	1.1	1.2
Estimated Total Cost Impact	43.6–59.4	66.3–82.1

Assumptions specific to the estimates for each individual provision are explained below.

• *SNF Three Day Prior Stay.* A three-percent increase in SNF admissions directly from the community was assumed.

• *Treatment use of Investigational Drugs for COVID–19 or Associated Sequelae under Expanded Access.* The Expanded Access cost estimate assumes that investigational drugs for the treatment of COVID–19 under expanded access available during the period of the national emergency would include convalescent plasma (approximately $1,000 per patient), a new hospital-based infusion antiviral ($2,500 per patient), and two oral antivirals ($200 per 10-pack). The number of investigational drugs available to TRICARE beneficiaries, the extent to which the FDA authorizes expanded access to such investigational drugs for treatment use, and the length of time until marketing approval of the drug by FDA, or emergency use authorization, are highly uncertain.

• *Temporary Hospitals and Freestanding ASCs Registering as Hospitals.* This zero cost estimate assumes that inpatient care provided in these alternate sites is care that would have been reimbursed under TRICARE but for a lack of acute care hospital facility space (*i.e.,* we do not estimate that there would be any induced demand because of an increase in facilities). Additionally, it assumes that while reimbursement for outpatient procedures in freestanding ASCs would be higher than had those procedures been reimbursed under the traditional reimbursement rates for freestanding ASCs, the number of facilities choosing to register as hospitals is likely to be small enough to have a negligible impact on the budget.

• *DRG Increase for COVID–19 Patients.* Under a three-wave scenario, we assumed a total of 34,300 TRICARE beneficiaries under the age of 65 would be hospitalized with diagnoses related to COVID–19 during the 18-month period. Total cost for hospitalization of these patients would be $390M, with $51M as the incremental cost increase of implementing the 20 percent DRG increase. We did not include Medicare-eligible patients in our estimate, as TRICARE's cost-share would not change for these patients.

• *NTAPs.* We assumed TRICARE NTAPs would be a similar percentage of inpatient spending to Medicare's NTAP usage and that TRICARE would adopt all of Medicare's NTAPs. This amount will vary depending on the number of new NTAPs adopted by Medicare each year, the extent to which Medicare-identified emerging technologies are covered under TRICARE's statutory and regulatory requirements, and the extent to which TRICARE's population utilizes these technologies. The costs for this provision may overestimate the incremental costs of this regulatory change, because many of these claims are being approved on a case-by-case basis by the Director, DHA, under waiver authority. In those cases, adopting NTAPs is likely to reflect a cost savings, as waivers are typically paid at billed charges.

• *HVBP Program.* Due to our retroactive implementation of the HVBP Program, we anticipate that those hospitals qualifying for a positive adjustment for prior claims would do so, while those with negative adjustments or adjustments close to zero dollars would not. This would result in a cost in the first year, with claims in following years assumed to be budget neutral.

• *LTCH Site Neutral Payments.* TRICARE is in the process of phasing in Medicare's site-neutral payment rates. This cost estimate assumes that phase-in is halted and all TRICARE LTCH claims are paid at the full LTCH PPS rate.

Depending on the impact of certain provisions of this IFR, some cost savings could be achieved from a reduction in hospitalization rates (*i.e.,* use of investigational drugs for treatment use under expanded access), estimated from no savings to $40M over 18 months. The amount of cost-savings achieved will be determined by the therapies developed, how widespread their usage is, the extent to which the therapies are authorized for treatment use under expanded access, the effectiveness of the therapies in reducing hospitalizations and/or the use of mechanical ventilators, and how long the therapies remain investigational before transitioning to FDA-approval or emergency use authorization.

Any benefits achieved in reduced hospitalizations and/or mechanical ventilator use are also benefits to TRICARE beneficiaries, for whom avoidance of more serious COVID–19 illness is of paramount concern. While we cannot estimate the value of this avoidance in quantitative figures, the potential long-term consequences of a serious COVID–19 illness, including permanent cardiac or lung damage, are not insignificant. If beneficiaries are able to access emerging therapies that prevent long-term consequences (including death), this will be a benefit to the beneficiary.

The largest creators of costs under this IFR (reimbursement changes) are not anticipated or intended to create any cost savings. However, these changes will benefit TRICARE institutional providers and take stress off the entire health care system by ensuring adequate reimbursement during the PHE, at a time during which hospitals are losing revenue due to reduced elective procedures and patients who delay care due to fears of contracting COVID–19 during health care encounters. Ensuring a robust health care system is of benefit to our beneficiaries and the general public, particularly in rural or underserved areas, even though this benefit is not quantifiable.

e. Benefits

The benefit changes in this IFR will positively impact TRICARE beneficiaries diagnosed with COVID–19 by ensuring that they have access to treatment with investigational drugs authorized by the FDA under expanded access (not in clinical trial settings). This change expands the therapies available to TRICARE beneficiaries while doing so in settings that ensure informed consent of the beneficiary, and that the benefits of treatment outweigh the potential risks. Providers will be positively impacted by being able to provide their patients with a broader range of treatment options. The expansion of providers who can provide

inpatient and outpatient hospital services positively benefits beneficiaries, who will have increased access to acute care facilities, and providers, who will have increased options for providing their beneficiaries with said care. SNFs and acute care hospitals will be positively impacted by the ability to more quickly transition patients from acute care to skilled nursing care. LTCH and inpatients hospitals will be positively impacted by increased reimbursement when caring for patients with COVID–19.

f. Alternatives

The DoD considered several alternatives to this IFR. The first alternative involved taking no action. Although this alternative would be the most cost neutral for DHA, it was rejected as not addressing the urgent medical needs of the beneficiary population in response to the COVID–19 pandemic. Additionally, it would fail to fulfill the statutory mandate that TRICARE reimburse like Medicare.

The second alternative the DoD considered was implementing a more limited benefit change for COVID–19 patients by not covering investigational drugs for treatment use under expanded access. While this would have the benefit of reimbursing only care that has more established evidence in its favor, this alternative is not preferred because early access to treatments is critical for TRICARE beneficiaries given the rapid progression of the disease and the lack of available approved treatments.

B. Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Secretary certifies that this IFR is not subject to the flexibility analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any one year). Individuals and states are not included in the definition of a small entity. The provisions of this IFR that are most likely to have an economic impact on hospitals and other health care providers are the reimbursement provisions adopted to meet the statutory requirement that we reimburse like Medicare. As its measure of significant economic impact on a substantial number of small entities, HHS uses an adverse change in revenue of more than 3 to 5 percent. While TRICARE is not required to follow this guidance in the issuance of our rules, we provide this metric for context, given that these temporary changes align with similar changes made by Medicare.

Given that the temporary reimbursement provisions of this IFR increase reimbursement for hospitals and LTCHs, we find that these provisions would not have an adverse impact on revenue for hospitals and, therefore, would not have a significant impact on these hospitals and other providers meeting the definition of small business. We also find that NTAPs, given that they increase revenue under the DRG system, would not have an adverse impact on hospitals and providers. The HVBP program would not reduce revenue for a hospital being penalized under the system beyond the HHS threshold. Lastly, coverage of investigational drugs for treatment under expanded access and allowing temporary hospitals and freestanding ASCs to register as inpatient hospitals are not expected to result in any adverse economic impact on hospitals or other health care providers.

Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

C. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

D. Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. This IFR will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

E. Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been determined that 32 CFR part 199 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

F. Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates an IFR (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This IFR does not preempt State law or impose substantial direct costs on State and local governments.

List of Subjects in 32 CFR Part 199

Administrative practice and procedure, Claims, Dental, Fraud, Health care, Health insurance, Individuals with disabilities, Mental health programs, and Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Amend § 199.4 by:
■ a. Adding a parenthetical sentence after the third sentence of paragraph (b)(3)(xiv) introductory text; and
■ b. Adding a sentence at the end of the second paragraph of the NOTE to paragraph (g)(15)(i)(A) and redesignating the note as ''Note to paragraph (g)(15)(i)(A)''.

The additions read as follows:

§ 199.4 Basic program benefits.

* * * * *

(b) * * *

(3) * * *

(xiv) * * * (The three-day hospital stay requirement is waived for the duration of the President's national emergency for the coronavirus disease 2019 (COVID–19) outbreak.) * * *

* * * * *

(g) * * *

(15) * * *

(i) * * *

(A) * * *

Note to paragraph (g)(15)(i)(A): * * * * * * For the duration of the President's national emergency in response to the COVID–19 outbreak, TRICARE will cost-share investigational drugs provided for the treatment of COVID–19 under expanded access.

* * * * *

■ 3. Amend § 199.6 by adding a note following paragraph (b)(4)(i)(I) to read as follows:

§ 199.6 TRICARE-authorized providers.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(I) * * *

Note to paragraph (b)(4)(i)(I):

For the duration of Medicare's ''Hospitals without Walls'' initiative for the coronavirus

disease 2019 (COVID–19) outbreak, certain temporary hospitals and freestanding ambulatory surgical centers (ASCs) that enroll with Medicare as hospitals may be temporarily exempt from certain institutional requirements for acute care hospitals in this paragraph 199.6(b)(4)(i), as determined by the Director, Defense Health Agency (DHA), or designee, to ensure access to acute inpatient care during the COVID–19 outbreak.

* * * * *

■ 4. Amend § 199.14 by:
■ a. Revising paragraph (a)(1)(iii)(E)(*2*);
■ b. Adding paragraphs (a)(1)(iii)(E)(*5*) and (*6*); and
■ c. Adding a note following paragraph (a)(9)(i).

The revision and additions read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *
(1) * * *
(iii) * * *
(E) * * *

(*2*) *Wage adjustment.* CHAMPUS will adjust the labor portion of the standardized amounts according to the hospital's area wage index. The wage adjusted DRG payment will also be multiplied by 1.2 for an individual diagnosed with COVID–19 and/or Coronavirus discharged during the Secretary of Health and Human Services' declared public health emergency (PHE).

* * * * *

(*5*) *Additional payment for new medical services and technologies.* TRICARE will, for TRICARE authorized services/supplies, adopt the Medicare New Technology Add On Payments (NTAPs) adjustment to DRGs for new medical services and technologies as implemented under 42 CFR 412.87, when determined by the Assistant Secretary of Defense for Health Affairs (ASD(HA)), as practicable. The Director, Defense Health Agency (DHA), shall provide notice of the issuance of policies and guidelines adopting such adjustments together with any variations deemed necessary to address unique issues involving the beneficiary population or program administration.

(6) *Hospital Value Based Purchasing.* TRICARE will adopt the Medicare Hospital Value Based Purchasing (HVBP) Program adjustments to DRGs to incentivize hospitals as implemented under 42 CFR 412.160, when determined by the ASD(HA), as practicable. The Director, DHA, shall provide notice of the issuance of policies and guidelines adopting such adjustments together with any variations deemed necessary to address unique issues involving the beneficiary population or program administration.

* * * * *

(9) * * *
(i) * * *

Note to paragraph (a)(9)(i):

LTCH admissions that are in response to the COVID–19 declared PHE and occur during the COVID–19 PHE period will be reimbursed the LTCH PPS standard Federal rate.

* * * * *

Dated: August 31, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–19594 Filed 9–1–20; 1:00 pm]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0048; FRL–10013–00–Region 1]

Air Plan Approval; Rhode Island; Reasonably Available Control Technology for the 2008 and 2015 Ozone Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a State Implementation Plan (SIP) revision submitted by the State of Rhode Island. The SIP revision consists of a demonstration that Rhode Island meets the requirements of reasonably available control technology (RACT) for the two precursors for ground-level ozone, oxides of nitrogen (NO_X) and volatile organic compounds (VOCs), set forth by the Clean Air Act (CAA or Act) with respect to the 2008 and 2015 ozone National Ambient Air Quality Standards (NAAQSs or standards). Additionally, we are approving specific regulations that implement the RACT requirements by limiting air emissions of NO_X and VOC pollutants from sources within the State. This action is being taken in accordance with the Clean Air Act.

DATES: This rule is effective on October 5, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2020–0048. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: David L. Mackintosh, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109–3912, tel. 617–918–1584, email *Mackintosh.David@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. Background and Purpose

On June 18, 2020 (85 FR 36823), EPA issued a notice of proposed rulemaking (NPRM) for the State of Rhode Island. In the NPRM, EPA proposed approval of a SIP revision submitted by Rhode Island on September 20, 2019. The SIP revision contains a certification that Rhode Island has met all RACT requirements for the 2008 and 2015 8-hour ozone NAAQSs and updates the SIP with the following changes to Title 250 Rhode Island Code of Regulations (RICR), Chapter 120 Air Resources, Subchapter 05 Air Pollution Control: Part 0 General Definitions Regulation; Part 11 Petroleum Liquids Marketing and Storage; Part 15 Control of Organic Solvent Emissions; Part 19 Control of Volatile Organic Compounds from Coating Operations; Part 21 Control of Volatile Organic Compound Emissions from Printing Operations; Part 25 Control of Volatile Organic Compound Emissions from Cutback and Emulsified Asphalt; Part 26 Control of Organic Solvent Emissions from Manufacturers of Synthesized Pharmaceutical Products; Part 27 Control of Nitrogen Oxide Emissions; Part 35 Control of Volatile Organic Compounds and Volatile Hazardous Air Pollutants from