Office of Foreign Assets Control

Russian Harmful Foreign Activities Sanctions Regulations

31 CFR Part 587

General License No. 32

Authorizing the Wind Down of Transactions Involving Amsterdam Trade Bank NV

(a) Except as provided in paragraph (b) of this general license, all transactions ordinarily incident and necessary to the wind down of transactions involving Amsterdam Trade Bank NV, or any entity in which Amsterdam Trade Bank NV owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by Executive Order (E.O.) 14024 are authorized through 12:01 a.m. eastern daylight time, July 12, 2022.

(b) This general license does not authorize:

(1) Any transactions prohibited by Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any transactions prohibited by Directive 4 under E.O. 14024, *Prohibitions Related to Transactions Involving the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, and the Ministry of Finance of the Russian Federation;* or

(3) Any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control.

Dated: May 5, 2022.

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–11760 Filed 5–31–22; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DoD–2020–HA–0040; and DoD–2020–HA–0050]

RIN 0720–AB81; 0720–AB82; and 0720–AB83

TRICARE Coverage and Reimbursement of Certain Services Resulting From Temporary Program Changes in Response to the COVID–19 Pandemic

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Assistant Secretary of Defense for Health Affairs (ASD(HA)) issues this final rule related to certain provisions of three TRICARE interim final rules (IFRs) with request for comments issued in 2020 in response to the novel coronavirus disease 2019 (COVID–19) public health emergency (PHE). Temporary coverage of telephonic office visits is made permanent in this final rule, with its adoption expanded beyond the pandemic; the temporary telehealth cost-share waiver is terminated; and the temporary waiver of certain acute care hospital requirements and permanent adoption of Medicare New Technology Add-on Payments for new medical items and services are modified, as further discussed in the **SUPPLEMENTARY INFORMATION** section of this rule

DATES: This rule is effective July 1, 2022, except for instruction 4 (the provision modifying temporary hospitals) which is effective on June 1, 2022. Effective July 1, 2022 the interim final rules amending 32 CFR part 199, which were published at 85 FR 27921, May 12, 2020, and 85 FR 54914, September 3, 2020, are adopted as final with changes, except for the note to paragraph 199.4(g)(15)(i)(A), published at 85 FR 54923, September 3, 2020, which remains interim.

FOR FURTHER INFORMATION CONTACT: Erica Ferron, Defense Health Agency, Medical Benefits and Reimbursement Section, 303–676–3626 or *erica.c.ferron.civ@mail.mil.* Sharon Seelmeyer, Defense Health Agency, Medical Benefits and Reimbursement Section, 303–676–3690 or *Sharon.l.seelmeyer.civ@mail.mil,* Diagnosis Related Groups, Hospital Value Based Purchasing, Long Term Care Hospitals, and New Technology Add-On Payments.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Rule

In response to the novel coronavirus (SARS–CoV–2), which causes COVID–19, and the President's declared national emergency for the resulting pandemic (Proclamation 9994, 85 FR 15337 (March 18, 2020)), the ASD(HA) issued three IFRs in 2020 to make temporary modifications to TRICARE regulations in order to better respond to the pandemic. The first IFR, published in the FR on May 12, 2020 (85 FR 27921), temporarily: (1) Modified the TRICARE regulations to allow for coverage of medically necessary telephonic (audio-only) office visits; (2) permitted interstate and international practice by TRICARE providers when such practice was permitted by state, federal, or host-nation law; and (3) waived cost-shares and copayments for covered telehealth services for the duration of the COVID–19 pandemic.

The second IFR, published in the FR on September 3, 2020 (85 FR 54914) temporarily: (1) Waived the three-day prior hospital qualifying stay requirement for skilled nursing facilities (SNFs); (2) added coverage for the treatment use of investigational drugs under expanded access authorized by the U.S. Food and Drug Administration (FDA) when indicated for the treatment of COVID–19; (3) waived certain provisions for acute care hospitals in order to permit TRICARE authorization of temporary hospital facilities and freestanding ambulatory surgical centers (ASCs) providing inpatient and outpatient services to be reimbursed; (4) revised the diagnosis related group reimbursement (DRG) at a 20 percent higher rate for COVID–19 patients; and (5) waived certain requirements for long term care hospitals (LTCHs). The second IFR also included two permanent provisions adopting Medicare's NTAPs adjustment to DRGs for new medical services and technologies and adopting Medicare's Hospital Value Based Purchasing (HVBP) Program.

The third IFR, published in the FR on October 30, 2020 (85 FR 68753) added coverage of National Institute of Allergy and Infectious Disease (NIAID)-sponsored clinical trials when for the prevention or treatment of COVID–19 or its associated sequelae.

After publication of each IFR, DoD evaluated the appropriateness of each temporary measure for continued use throughout the national emergency for COVID–19, as well as to determine if it would be appropriate to make any of the provisions permanent within the

TRICARE program. After analysis of the risks, benefits, and costs of each provision, as well as a review of comments, the ASD(HA) issues this final rule to make the following changes:

a. 32 CFR 199.4(g)(52) Telephone Services: The IFR temporarily modified this regulation provision which excluded telephone services (audio-only) except for biotelemetry. This final rule revises this regulatory exclusion and permanently modifies 32 CFR 199.4(c)(1)(iii) Telehealth Services to add coverage for medically necessary telephonic office visits, in all geographic areas where TRICARE beneficiaries reside. A telephonic office visit is a reimbursable telephone call between a beneficiary, who is an established patient, and a TRICARE-authorized provider. This is considered a type of telehealth modality under the TRICARE program. Specifically, this change will allow providers to be reimbursed for medically necessary care and treatment provided to beneficiaries over the telephone, when a face-to-face, hands-on visit is not required, and a two-way audio and video telehealth visit is not possible. The telephonic office visit should be a valid medical visit in that there is an examination of the patient's history and chief complaint along with clinical decision making performed by a provider. Telephonic provider-to-provider consults which are audio-only, but otherwise meet the definition of a covered consultation service are also covered under this final rule. Telephone calls of an administrative nature (*e.g.,* appointment scheduling), routine answering of questions, prescription refills, or obtaining test results are not medical services and are not reimbursable.

DoD implemented temporary coverage of telephonic office visits effective May 12, 2020, in order to provide beneficiaries the option to obtain some medical services safely from home, reducing their exposure to COVID–19 and to minimize potential spread of the illness. In order to determine if telephonic office visits should be converted to a permanent telehealth benefit, DoD analyzed claims data from TRICARE private sector care and reviewed published industry information from: Medicare; health insurance plans; and physicians' professional organizations regarding telephonic office visits. The TRICARE claims data between mid-March and mid-September 2020 indicates beneficiary utilization of telephonic office visits is a small portion of all telehealth claims. Medicare and health insurance plans reported data indicating substantial utilization of telephonic office visits. Physicians' professional organizations including the American College of Physicians (ACP) and the American Medical Association (AMA) issued statements reporting physicians' favorable experiences with telephonic office visits. Furthermore, the DoD received positive public comments regarding telephonic office visits including multiple requests for the agency to consider it as a permanent benefit. After thoughtful consideration of these facts, and through this final rule revising the regulatory exclusion prohibiting reimbursement of telephonic (audio-only) office visits, the DoD will revise the exclusion of audio-only telephonic services and add medically necessary telephonic office visits as a covered telehealth service under the TRICARE Basic Benefit. In addition, 32 CFR 199.2 Definitions will be amended by this final rule to include definitions of ''Biotelemetry,'' ''Telephonic consultations,'' and ''Telephonic office visits'' as related to the modified telehealth service regulation provision.

b. 32 CFR 199.6(b)(4)(i)(I): The temporary waiver of certain acute care hospital requirements for temporary hospitals and freestanding ambulatory surgery centers during the COVID–19 pandemic from the second COVID IFR remains in effect, with modifications. The modification temporarily allows any entity that enrolled with Medicare as a hospital through Medicare's Hospitals Without Walls initiative to become a TRICARE-authorized hospital that may be considered to meet the requirements for an acute care hospital listed under paragraph 199.6(b)(4)(i). These entities may provide any inpatient or outpatient hospital services, when consistent with the State's emergency preparedness or COVID–19 pandemic plan and when they meet the Medicare hospital Conditions of Participation (CoP), to the extent not waived. Under Medicare's Hospitals Without Walls initiative, Centers for Medicaid and Medicare Services (CMS) relaxed certain requirements to allow ASCs and other interested entities, such as licensed independent emergency departments, to temporarily enroll as Medicare-certified hospitals and receive reimbursement for hospital inpatient and outpatient services. Although CMS ceased accepting new enrollments into the Hospitals Without Walls initiative, effective December 1, 2021, those entities that were previously enrolled under the initiative continue to be enrolled and receive reimbursement for hospital inpatient and outpatient services. The CMS memorandum eliminating future enrollments into the Hospitals Without Walls initiative, does not impact any of the changes from the initial IFR or in this final rule, as both require a provider to first be enrolled with CMS as a hospital under the initiative to register with TRICARE as a hospital and receive reimbursement as a hospital.

The ASD(HA) also recognizes the need for increased access to inpatient and outpatient care during the COVID–19 pandemic. In the IFR, we temporarily permitted temporary hospitals and freestanding ASCs that registered with Medicare as hospitals to be reimbursed as acute care hospitals (85 FR 54914). We are modifying this expanded coverage of inpatient and outpatient care by allowing any entity enrolled with Medicare as a hospital on a temporary basis to also be considered a TRICARE-authorized hospital and receive reimbursement for inpatient and outpatient institutional charges under the TRICARE DRG payment system, Outpatient Prospective Payment System (OPPS), or other applicable hospital payment system allowed under Medicare's Hospitals Without Walls initiative, to the extent practicable. In order to reduce burden on these providers during the pandemic, we are not developing any regulatory requirements for participation in TRICARE and will instead permit any entity that registers with Medicare as a hospital under their Hospitals Without Walls initiative to be considered a TRICARE-authorized hospital. To further reduce the burden on providers and the TRICARE program, this final rule will allow the Defense Health Agency (DHA) to adopt any requirement related to Medicare's Hospital without Walls initiative through administrative policy, when determined practicable, without going through the lengthy regulatory process. This provision will be effective the date published in the FR through the expiration of Medicare's Hospitals Without Walls initiative. Upon conclusion of Medicare's initiative or when a facility loses its hospital status with Medicare, whichever occurs earlier, the entity will no longer be considered an authorized hospital under TRICARE and will not be reimbursed for institutional charges unless it otherwise qualifies as an authorized institutional provider under paragraph 199.6(b)(4). While vaccination has slowed the spread of COVID–19 in many areas of the U.S., the virus remains a deadly threat for those patients who do contract it and require acute care treatment. Additionally,

access to acute care treatment for other injury and illnesses in areas where there is a COVID–19 resurgence remains essential. The ASD(HA) finds it necessary to make this provision of the final rule effective upon publication of the final rule.

c. 32 CFR 199.14(a)(1)(iv): Special Programs and Incentive Payments. This final rule creates new paragraph 199.14(a)(1)(iv) to more appropriately categorize the NTAP and HVBP payments. It moves the NTAP provisions from paragraph 199.14(a)(1)(iii)(E)(*5*) to 199.14(a)(1)(iv)(A), and moves the HVBP provision from paragraph 199.14(a)(iii)(E)(*6*) to 199.14(a)(1)(iv)(B). For the NTAP provisions, TRICARE: (1) Shall apply Medicare NTAP adjustments to TRICARE covered services and supplies, except for pediatric (defined for NTAPs as pertaining to patients under the age of 18, or who are treated in a children's hospital or in a pediatric ward) services and supplies; (2) shall modify NTAP reimbursement adjustment rates for NTAPs at 100 percent of the average cost of the technology or 100 percent of the costs in excess of the Medicare Severity-Diagnosis Related Group (MS–DRG) payment for the case for pediatric beneficiaries; and (3) may create a reimbursement adjustment for TRICARE NTAPs, specific to the TRICARE beneficiary population under age 65 in the absence of a Medicare NTAP adjustment, using criteria similar to Medicare criteria for eligible new technologies outlined in 42 CFR 412.87 and the Medicare reimbursement criteria outlined in 42 CFR 412.88. Under the statutory authority to pay like Medicare for like services and items when practicable in 10 U.S.C. 1079(i)(2), the ASD(HA) has determined that, generally, the NTAP reimbursement methodology is practicable for TRICARE to adopt for any otherwise covered services and supplies with a Medicare NTAP, under the same conditions as approved by Medicare. However, the ASD(HA) finds it impracticable to use Medicare's NTAPs for TRICARE's pediatric patients due to the lack of a significant pediatric population within Medicare. To address the unique TRICARE beneficiary population of pediatric patients, this rule establishes reimbursement of pediatric NTAPs at 100 percent of the costs in excess of the MS–DRG payment. Lastly, when TRICARE covers new technologies that are not covered by Medicare or do not have a Medicare NTAP due to differing populations (*e.g.,* biologics used solely by pediatric patients), the ASD(HA) finds it practicable to establish a TRICARE NTAP category and methodology whenever necessary. In these instances, the Director, DHA, may issue implementation instructions listing the specific TRICARE NTAPs on the website: *www.health.mil/ntap.*

d. 32 CFR 199.17(l)(3): The cost-share and copayment waiver for telehealth services during the COVID–19 pandemic was implemented in TRICARE's first COVID–19 IFR in response to efforts by federal, state, and local governments to encourage individuals to stay at home, avoid exposure, and to reduce possible transmission of the virus. When the rule was published, there was a high degree of uncertainty surrounding the potential availability of a vaccine. With the approval or emergency use authorization of several vaccines by the U.S. Food and Drug Administration, the widespread availability of such vaccines throughout the United States, and the elimination of stay-at-home orders by most States and localities, this provision is no longer necessary. As such, the ASD(HA) is terminating the waiver of cost-shares and copayments for telehealth services on the effective date of this final rule, or upon expiration of the President's national emergency for COVID–19, whichever occurs earlier.

e. The DoD continues to evaluate potential permanent adoption of the treatment use of investigational drugs under expanded access and NIAID-sponsored clinical trials and will publish a final rule at a future date; until such publication, the two benefits remain in effect without modification as temporarily implemented in the second and third IFRs. These two benefits remain in effect through the end of the President's national emergency for COVID–19, unless modified by future rulemaking. Comments received on those two provisions during the IFR comment periods will be addressed in that final rule.

f. All temporary regulation changes made by the three COVID–19-related IFRs not otherwise addressed in this final rule remain in effect as stated in the IFR under which they were implemented until such time as the conditions for their expiration are met.

g. The HVBP Program is permanently adopted and is moved from 32 CFR 199.14(a)(1)(iii)(E)(*6*) to 32 CFR 199.14(a)(1)(iv)(B); there are otherwise no modifications from the second IFR.

B. Summary of Major Provisions

a. Changes to the TRICARE Benefit

Telephonic Office Visits

A telephonic office visit is an easy-to-use telehealth modality that has many benefits. A telephonic office visit consists of a beneficiary, who is an established patient, calling his/her provider to discuss an illness (including mental illness), injury, or medical condition. During the conversation the provider will ask questions regarding the symptoms and determine if they can proceed with the telephonic office visit or if based on the information he/she reported, a face-to-face, hands-on visit is in fact medically necessary. If they proceed with the telephonic office visit, typically the provider will have the beneficiary's medical record open for review during the call, offer medical advice, and may place an order for a prescription or lab tests. During the COVID–19 pandemic, telephonic office visits have been instrumental in keeping beneficiaries safer at home with less risk of exposure to COVID–19 for conditions which a face-to-face and hands-on visit is not medically necessary. Telephonic office visits are also highly desirable for beneficiaries who reside in rural areas and/or areas where health care services are scarce. Likewise, beneficiaries without access to the internet and/or computers, smartphones, or tablets to conduct two-way audio-video telehealth visits also greatly benefit from coverage of telephonic office visits. DoD will continue to offer coverage of telephonic office visits through the end of the pandemic and with this final rule DoD will revise the telephone services (audio-only) regulatory exclusion in order to make this a permanent telehealth benefit available to beneficiaries in all geographic locations, when such care is medically necessary and appropriate.

To understand the use of telephonic office visits during the COVID–19 pandemic, the DoD analyzed claims data from TRICARE private sector care and reviewed published industry information from: Medicare; health insurance plans; and physicians' professional organizations regarding telephonic office visits. TRICARE private sector claims data from mid-March 2020 through mid-September 2020 indicates there were a total of 80,541 telephonic office visits conducted. Telephonic office visits were an average 2.1 percent of all telehealth services provided. Telehealth services were 5.7 percent of all outpatient professional visits. In August 2020, a Medicare Advantage Issue Brief

reported, ''Three million telehealth visits with Medicare beneficiaries between mid-March and mid-June were conducted via telephone indicating the preference for [telephonic office visits].'' [1] Health insurance plans including Security Health Plan and Kaiser Permanente reported 75 percent and 85 percent respectively of their telehealth visits as telephonic office visits.[2] The AMA stated, ''Doctors have reported that they have been able to conduct successful [telephonic office visits] with patients, in lieu of in-person or telehealth visits, obtaining about 90 percent of the information they would collect using audio and video capable equipment.'' [3] In March 2020, the ACP began writing letters to CMS requesting pay parity for telephonic office visits. On April 30, 2020, CMS responded to the ACP's requests announcing that it was increasing payments for telephonic office visits to match payments of similar office and outpatient visits.[4] TRICARE routinely updates its reimbursement rates in accordance with CMS updates, consistent with existing statutory requirements, when practicable. Note that CMS intends to only temporarily offer coverage for telephonic office visits for certain services during the public health emergency. However, although TRICARE is required to reimburse like Medicare to the extent practicable under the statute, TRICARE is not required to provide the exact same benefits as Medicare given the differences in populations served. Prior to the pandemic, DoD had a telehealth benefit that was more generous than what was offered under Medicare. Considering all of the data and industry information discussed, the DoD is finalizing its approach to permanently revise the telephone services (audio-only) regulatory exclusion and allow coverage of medically necessary and appropriate telephonic office visits for beneficiaries in all geographic locations.

In converting medically necessary telephonic office visits to a permanent benefit, the DoD will issue policy guidance describing coverage of medically necessary and appropriate telephonic office visits to ensure best practices and protect against fraud.

Entities Temporarily Enrolling as Hospitals

This final rule modifies the temporary waiver of certain acute care hospital requirements for TRICARE authorized hospitals in the IFR to allow any entity that has temporarily enrolled with Medicare as a hospital through their Hospitals Without Walls initiative (or enrolls in the future, should Medicare resume such enrollments) to temporarily become a TRICARE-authorized hospital under paragraph 199.6(b)(4)(i). These entities may provide any inpatient or outpatient hospital services, when consistent with the State's emergency preparedness or COVID–19 pandemic plan and when they meet the Medicare hospital CoP, to the extent not waived. While there are no direct corollaries in TRICARE regulation to the CoP being waived under Medicare, there do exist in TRICARE regulation certain requirements that would prevent allowing some facilities to be considered as acute care hospitals for the purposes of payment. Title 32 CFR 199.6(b)(3) and (4) list the requirements for providers to be considered TRICARE-authorized hospitals. It may not be possible for some entities to meet all of these requirements, such as providing primarily inpatient care or having Joint Commission (previously known as the Joint Commission on Accreditation of Hospitals) accreditation status or surveying of new facilities.

We continue to assert, as we did in the IFR, that these institutional requirements are necessary for TRICARE-authorized acute care hospitals. We also note there is no requirement to have a TRICARE benefit that matches Medicare's benefit, or for TRICARE to authorize all providers that are providers under Medicare. Both TRICARE's statutory authority and population differ from Medicare's, so it is appropriate for TRICARE to continue to manage its authorized provider program separately from Medicare's. During the COVID–19 pandemic, however, it is important for TRICARE to ensure swift access to inpatient and outpatient care, to include leveraging Medicare's flexibilities for acute care facilities. Under Medicare's Hospitals Without Walls initiative, CMS relaxed certain requirements to allow ASCs and other interested entities, such as licensed independent freestanding emergency departments, to temporarily enroll as Medicare-certified hospitals and to receive reimbursement for hospital inpatient and outpatient services. In the previously-published IFR, we extended coverage of acute care hospitals to include temporary hospitals and freestanding ASCs that registered with Medicare as hospitals to be reimbursed as hospitals under TRICARE. This final rule expands the original temporary hospital waiver by temporarily permitting any entity to qualify as an acute care hospital under TRICARE so long as it had enrolled with Medicare as a hospital under the Hospitals Without Walls initiative prior to the December 1, 2021 memorandum by which CMS terminated further enrollments (or enrolls in the future, should CMS resume enrollments).

In the IFR, it was not our intent to maintain a regulatory list of qualifying providers in § 199.6 that are eligible to enroll with Medicare under their Hospitals Without Walls initiative or to adopt such changes through the regulatory process, which imposes an unnecessary administrative burden on the DHA and delays coverage for providers and patients, as paragraph 199.6(b)(4)(i) may need to be continually updated to keep current with Medicare changes during the pandemic. Therefore, this final rule modifies the temporary regulation change from the IFR at paragraph 199.6(b)(4)(i) to allow any entity enrolled with Medicare as a hospital to temporarily become a TRICARE-authorized acute care hospital, and receive reimbursement for inpatient and outpatient institutional charges under the TRICARE DRG payment system, OPPS, or other applicable hospital payment system allowed under Medicare's Hospitals Without Walls initiative (when determined practicable). The ASD(HA) will implement Medicare's requirements for such entities through administrative guidance (*e.g.,* the TRICARE manuals) to ensure TRICARE requirements for such facilities are consistent with the most current Medicare requirements under the Hospitals Without Walls initiative.

Under this provision, facilities that convert into hospitals and are Medicare-certified hospitals through an emergency waiver authority under Section 1135 of the Social Security Act and are operating in a manner consistent with their State's emergency plan in effect during the COVID–19 pandemic will be eligible for reimbursement by TRICARE for covered inpatient and outpatient services under the applicable hospital payment system. Once an entity ends, terminates, or loses its hospital status under Medicare, the facility will no longer be considered a TRICARE-authorized acute care hospital effective the date when Medicare

[1] ''Issue Brief: Audio-only Telehealth Visits Essential for Use in Medicare Advantage Risk Adjustment'', Better Medicare Alliance. August 2020. Web. Accessed 15 Dec. 2020.

[2] *Ibid.*

[3] ''Amid pandemic, CMS should level field for phone E/M visits'', Kevin B. O'Reilly, *AMA Digital,* April 20, 2020. Web. Accessed 15 Dec. 2020

[4] ''CMS Announcement of Pay Parity for Telephone Calls Answers a TOP ACP Priority'' American College of Physicians. Statement attributable to Jacqueline Fincher, President, American College of Physicians. April 30, 2020. Web. Accessed 15 Dec. 2020.

deactivated the entity's hospital billing privileges. While we are temporarily amending the institutional provider requirements under paragraph 199.6(b)(4)(i), we are still requiring that these facilities meet Medicare's CoP (to the extent not waived) established for this Presidential national emergency. This change will improve beneficiary access to medically necessary care and may mitigate hospitals' lack of capacity and shortages of resources during the pandemic. This change is temporary for the duration of Medicare's ''Hospitals Without Walls'' initiative.

b. Reimbursement Modifications Consistent With Medicare Requirements

NTAPs

NTAP Reimbursement

As stated in the second IFR (85 FR 54914), for care rendered in an inpatient setting, TRICARE shall reimburse services and supplies with Medicare NTAPs using Medicare's NTAP payment adjustments for only those services and supplies that are an approved benefit under the TRICARE Program. Title 10 U.S.C. 1079(i)(2) requires TRICARE to reimburse covered services and supplies using the same reimbursement rules as Medicare, when practicable. However, this provision is not self-executing, so this FR permanently adopts the Medicare NTAP methodology. TRICARE shall also adopt future NTAP modifications published by CMS, including modifications to the NTAP methodology and the list of new technologies to which NTAPs are applied.

Pediatric Reimbursement

Per the authority provided in 10 U.S.C. 1079(i)(2), the ASD(HA) may determine that the Medicare NTAP methodology is not practicable for certain populations. One such population is TRICARE's pediatric population, which, as used in relation to the NTAP provisions in this final rule, is defined as individuals under the age of 18, or who are being treated in a children's hospital or in a pediatric ward. Since Medicare does not have a pediatric population to consider when establishing alternative reimbursements for new high-dollar technologies, the ASD(HA) has therefore determined it is not practicable to use Medicare's NTAPs for pediatric patients; instead, the NTAP adjustment should be modified to address the unique TRICARE beneficiary population of pediatric patients. Under this modification, TRICARE shall reimburse pediatric NTAP claims at 100 percent of the costs in excess of the MS–DRG. Paying these claims at 100 percent of the costs in excess of the MS–DRG increases the likelihood that all pediatric beneficiaries will receive medically necessary and appropriate treatment, especially pediatric beneficiaries with serious, life-threatening, and costly diseases.

High-Cost Treatments Without an NTAP

Some new, high-cost treatments are not identified as requiring an NTAP by CMS. This primarily occurs when a treatment for a rare, fatal disease may be appropriate for a beneficiary in TRICARE's population but is not appropriate for Medicare's population, which is typically age 65 and above. For example, Spinraza is a treatment for Spinal Muscular Atrophy, a rare genetic neuromuscular disease that primarily impacts infants and young children. Spinraza has a high-cost per treatment, but is reimbursed at substantially lower cost when administered in a hospital because it is included in the DRG reimbursement. CMS does not include Spinraza in its list of new technologies receiving an NTAP.

The ASD(HA) therefore finds it impracticable to reimburse such technologies using existing reimbursement methodologies, which do not allow sufficient rates for new, high-cost technologies during the first two or three years following FDA approval, after which, they are absorbed into the core DRG through the annual DRG update and calibration process. The ASD(HA) finds it practicable to establish a category of TRICARE NTAPs. This category may include services and supplies that are otherwise covered by TRICARE and that meet certain CMS eligibility criteria under 42 CFR 412.87. These eligibility criteria will ensure that DHA consistently and comprehensively evaluates new treatments when selecting which treatments may be approved for a TRICARE NTAP. Likewise, the reimbursement methodology for these TRICARE NTAPs shall follow the CMS reimbursement methodologies for Medicare NTAPs outlined in 42 CFR 412.88.

For these high-cost, new, life-saving treatments that do not qualify or otherwise have an NTAP designation from CMS but for which the existing Medicare reimbursement is not practicable for the TRICARE population, the Director, DHA, shall establish internal guidelines and policy for approving TRICARE NTAPs and adopting such adjustments together with any variations deemed necessary to address unique issues involving the beneficiary population or program administration. These include, but are not limited to the exact reimbursement methodology, the eligibility criteria, and the method for approving or denying a TRICARE specific NTAP. The approved TRICARE NTAPs shall be published at least annually on the website: *www.health.mil/ntap.*

c. Beneficiary Cost-Shares and Copayments

Termination of Cost-Share and Copayment Waivers for Telehealth During the COVID–19 Pandemic

The first IFR implemented a waiver of cost-shares and copayments (including deductibles) for all in-network authorized telehealth services for the duration of the COVID–19 pandemic (ending when the President's national emergency for COVID–19 is suspended or terminated, in accordance with applicable law and regulation). The purpose was to incentivize TRICARE beneficiaries to use telehealth services and avoid unnecessary in-person TRICARE-authorized provider visits, which could potentially bring them into contact with or aid the spread of COVID–19. The implementation of this provision was highly successful, with a significant number of beneficiaries shifting to the use of telehealth visits. Since this provision was enacted, however, several vaccines have been approved or granted emergency use authorization by the FDA and are now widely available throughout the United States. While concerns remain surrounding variants of the SARS–CoV–2 virus and herd immunity may not yet have been reached, states and localities are no longer enacting strict stay-at-home orders.

TRICARE spent approximately $20.6M on waived telehealth cost-shares and copayments in FY20 and another $71.4M through the end of September 2021. Due in part to flexibilities introduced in the IFRs discussed in this rule, and other program changes implemented via policy, the Defense Health Plan faces significant budget shortfalls. Termination of this provision will save the DoD $4.8M for every month it expires prior to the end of the national emergency, allowing DoD to focus resources on testing, vaccination efforts, and treatment for COVID–19-positive patients. We do not expect termination of this provision to have any impact on access to care, as beneficiaries will continue to have access to telehealth services and will be able to choose to continue using such services, or to visit their provider in-person, with the same cost-share applied to the service regardless of the

modality through which it was delivered.

Given the availability of vaccines, the reduction of stay-at-home orders, and the cost of waiving telehealth cost-sharing, the ASD(HA) finds it appropriate to expire the waiver on the effective date of this rule or the date of expiration of the President's national emergency for COVID–19, whichever is earlier. Telehealth services remain a covered benefit for TRICARE beneficiaries after the expiration of the cost-share/copayment waiver.

C. 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 under which TRICARE is administered 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 November 17, 2020 (85 FR 73193) by a final rule that added coverage of physical therapy and occupational services prescribed by a podiatrist.

The telephone services paragraph being modified by this final rule, paragraph 199.4(g)(52), was last temporarily modified with publication of the COVID–19-related IFR published on May 12, 2020 (85 FR 27921–27927), which temporarily permitted coverage of telephonic office visits for the duration of the President's national emergency for the COVID–19 pandemic. The telephone services regulatory exclusion was first published in the FR on April 4, 1977, with the comprehensive regulations implementing the ''Civilian Health and Medical Program of the Uniformed Services'' (42 FR 17972). Then, in 1984, the final rule, ''Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Cardiac Pacemaker Telephonic Monitoring'' (49 FR 35934) revised the exclusion to allow coverage of transtelephonic monitoring (a type of biotelemetry) of cardiac pacemakers. No other permanent revisions have been made to the telephone services paragraph.

Title 32 CFR 199.6 was last modified November 17, 2020 (85 FR 73196). This change updated terminology from doctors of podiatry or surgical chiropody to doctors of podiatric medicine or podiatrists and added podiatrists to the list of providers authorized to prescribe and refer beneficiaries to physical therapists and occupational therapists.

Title 32 CFR 199.14 was last permanently revised on September 3, 2020 (85 FR 54914–54924) with the addition of NTAPs and the HVBP Program under paragraph 199.14(a)(1)(iii)(E), which are being modified by this final rule.

Title 32 CFR 199.17 was last temporarily modified on May 12, 2020 (85 FR 27921–27927), with publication of the telehealth cost-share and copayment waiver being terminated by this final rule. This section was last permanently modified on February 15, 2019 (84 FR 4333), as part of the final rule implementing the TRICARE Select benefit plan. The revisions to § 199.17 included adding high-value services as a benefit under the TRICARE program, as well as copayment requirements for Group B beneficiaries. The 32 CFR 199.17(l) paragraph being modified by this IFR was created as part of the IFR that established the TRICARE Select benefit (82 FR 45438) during which a comprehensive revision of § 199.17 occurred. This paragraph did not exist prior to that revision and has only been modified once, with the addition of temporary telehealth cost-shares and copayment waivers.

III. Discussion of Comments & Changes

DoD sincerely appreciates all comments received on the IFRs published in response to the COVID–19 pandemic. We respond to comments for two of the IFRs below, separated by rule and impacted provision, except for comments on the treatment use of investigational new drugs, which will be discussed in a future final rule. We will also respond to comments related to TRICARE's third IFR published in 2020 in a future final rule. Except where otherwise modified in this final rule, we reaffirm the policies and procedures incorporated in the IFRs and incorporate the rationale presented in the preambles of the IFRs into this final rule.

A. IFR—TRICARE Coverage and Payment for Certain Services in Response to the COVID–19 Pandemic

This IFR was published in the FR (85 FR 27921) on May 12, 2020. Comments were accepted for 30 days until June 11, 2020. A total of 16 comments were received. Below is a summary of the comments and the Department's responses. Some commenters provided detailed feedback concerning the overall telehealth program, including its applicability to autism services, partial hospitalization programs, and behavioral health services, or regarding benefits outside of the scope of this rule, such as care provided in patients' homes. We thank the commenters for their feedback however, because these comments did not relate to telephonic office visits, provider licensing, or telehealth copays, we are unable to respond in detail to these comments. One commenter expressed concern about the use of nine months in the cost estimate and that provisions would expire after nine months. We note that the timeframe used for the cost estimates was based on early estimates for the pandemic and that each provision of the IFR only expires when the President's national emergency expires, except where modified by this final rule. There was no automatic expiration at nine months.

a. Telephonic Office Visits

1. Provisions of the IFR

The IFR allowed TRICARE beneficiaries to obtain telephonic office visits with providers for otherwise-covered, medically necessary care and treatment and allowed reimbursement to those providers during the COVID–19 pandemic. It provided a temporary exception to the regulatory exclusion prohibiting telephone services.

2. Analysis of Public Comments

The public comments regarding the temporary exception to the regulatory exclusion prohibiting telephone services were minimal. Commenters requested that DoD continue coverage of telephonic office visits after the COVID–19 pandemic and commenters requested telephonic office visits be expanded to a range of providers. This final rule includes regulatory text revising the prohibition on telephone services thereby allowing coverage of telephonic office visits permanently. This will include mental health and addiction treatment services when medically necessary and appropriate. Regarding the request to expand the range of providers who can provide telephonic office visits, there is nothing in TRICARE regulation or policy excluding specific provider types such as physical therapists, occupational therapists, registered dieticians, or diabetes counselors (note: Diabetes counselors must be registered dieticians to be TRICARE-authorized providers) from providing their services via telehealth, including telephonic office visits, so long as they otherwise meet program requirements, including that all care be medically necessary and appropriate.

Two commenters requested DoD make implementation of the telephonic office

visits retroactive, to either January 1, 2020, or March 1, 2020. The commenters noted that CMS adopted their allowance of telephonic office visits with a retroactive date. While DoD acknowledges that some providers may have provided telephonic office visits prior to the effective date of the IFR, DoD lacks the statutory authority to make the implementation retroactive. One commenter suggested DoD evaluate provider and patient satisfaction and health outcomes in determining whether to permanently adopt telephonic office visits. We agree that this information would be valuable but ultimately determined there was sufficient information from other sources to make a decision without it.

3. Provisions of Final Rule

No changes were made in response to public comments; however, this provision has been revised for the final rule (see next section for details).

b. Interstate and International Licensing of TRICARE-Authorized Providers

1. Provisions of the IFR

The IFR allowed providers to be reimbursed for interstate practice, both in person and via telehealth, during the global pandemic so long as the provider met the requirements for practicing in that State or under Federal law. It removed the requirement that the provider must be licensed in the state where practicing, even if that license is optional. For providers overseas, this allowed providers, both in person and via telehealth, to practice outside of the nation where licensed when permitted by the host nation.

2. Analysis of Public Comments

Comments received on the relaxation of licensing requirements for providers during the pandemic were generally supportive, with no comments received opposed. Several commenters suggested implementing the relaxed licensing requirement permanently for telehealth. DoD notes that licensing remains the purview of the States and that States generally require licensure in each State where practicing. DoD will continue to evaluate trends in licensing requirements for telehealth following the COVID–19 pandemic but will not be permanently adopting this provision at this time. We note that we continue to recognize (and recognized prior to the COVID–19 pandemic) interstate licensing agreements and reciprocal license agreements between states where a state considers a provider to be licensed at the full clinical practice level based on such an agreement.

3. Provisions of Final Rule

The final rule is consistent with the IFR.

c. Waiver of Copayments and Cost-Sharing for Telehealth Services

1. Provisions of the IFR

The IFR waived cost-shares and copayments for telehealth services for TRICARE Prime and Select beneficiaries utilizing telehealth services with an in-network, TRICARE-authorized provider during the President's declared national emergency for COVID–19.

2. Analysis of Public Comments

We received four comments regarding the waiving of telehealth cost-shares and copays, all of them supportive of the waiver, with one commenter also noting the negative effect of loss copay revenue for the DoD. Of the comments we received, three of them encouraged the DoD to continue to evaluate cost-sharing policies, and one comment also encouraged the DoD to make the telehealth copay and cost-share waiver permanent. One commenter recommended we apply the waiver of telehealth copays to copays associated with remote physiologic monitoring (RPM). RPM services of physiologic parameters including, but not limited to, monitoring of weight, blood pressure, pulse oximetry and respiratory flow rate shall be covered. RPM is considered an ancillary service and therefore ancillary copays and cost-shares shall apply.

We thank all the commenters for their support and feedback. TRICARE's temporary waiving of cost-shares and copays for all telehealth services was in line with initiatives by commercial insurers to incentivize telehealth care to help prevent the spread of COVID–19 and to reduce financial burdens on patients. TRICARE's cost-shares and copayments are set by law and require copayments and cost-sharing for telehealth services to be the same as if the service was provided in person. Section 718(d) of the National Defense Authorization Act of 2017 authorized the Secretary of Defense to reduce or eliminate copayments or cost-shares when deemed appropriate for covered beneficiaries in connection with the receipt of telehealth services under TRICARE. Given the national emergency caused by the COVID–19 pandemic, it was deemed appropriate to remove cost-shares and copayments for telehealth services during the pandemic, until there was no longer an urgent need to incentivize telehealth visits.

3. Provisions of Final Rule

The final rule is consistent with the IFR, except that this provision may terminate early. This provision of the final rule is being terminated early due to both the cost of waiving cost-shares and because there remain few, if any, stay-at-home orders for this provision to support. Defense Health Program dollars are better spent on testing, vaccination, and treatment for COVID–19, including a waiver of cost-shares for medically necessary COVID–19 testing, which remains in effect as a result of the CARES Act.

B. IFR—TRICARE Coverage of Certain Medical Benefits in Response to the COVID–19 Pandemic

This IFR was published in the FR on September 3, 2020 (85 FR 54914). Comments were accepted for 60 days until November 2, 2020. A total of four comments were received. Two were generally supportive of the provisions implemented in the IFR; we are grateful to the public for their support. Please see a summary of the comments and the DoD's responses below. Comments related to the treatment use of investigational drugs under expanded access will be discussed in a future final rule.

a. SNF 3-Day Prior Stay Waiver

1. Provisions of the IFR

The IFR temporarily waived the regulatory requirement that an individual be an inpatient of a hospital for not less than three consecutive calendar days before discharge from the hospital (three-day prior hospital stay) for coverage of a SNF admission for the duration of the COVID–19 public health emergency, consistent with a similar waiver under Medicare and TRICARE's statutory requirement to have a SNF benefit like Medicare's. The waiver will terminate when the Health and Human Services (HHS) PHE terminates.

2. Analysis of Public Comments

We received one comment on this provision of the IFR that was supportive of the waiver, but requested the DoD adopt another Medicare waiver; that is, the waiver of a 60-day wellness period.

We thank the commenter for their support and feedback. TRICARE is primary payer for Medicare/TRICARE dual eligible beneficiaries that have exhausted the Medicare 100-day SNF benefit (meeting TRICARE coverage requirements without any other forms of other health insurance (OHI)), and TRICARE is also primary payer for non-Medicare TRICARE beneficiaries who have no OHI and who meet the

TRICARE SNF coverage requirements. Because TRICARE covers patients immediately after benefits are exhausted, there is no current requirement for a 60-day wellness period under TRICARE.

3. Provisions of Final Rule

The final rule is consistent with the IFR.

b. Waiving of Acute Care Hospital Requirements for Temporary Hospital Facilities and Freestanding ASCs

1. Provisions of the IFR

The IFR temporarily exempted temporary hospital facilities and freestanding ASCs that enrolled as hospitals with Medicare from the institutional provider requirements for acute care hospitals described in paragraph 199.6(b)(4)(i). This allowed these facilities to provide inpatient and outpatient hospital services to improve the access of beneficiaries to medically necessary care. This change was 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. This waiver remains in effect through the end of Medicare's ''Hospitals Without Walls'' initiative.

2. Analysis of Public Comments

No public comments were received on this provision.

3. Provisions of Final Rule

No changes were made in response to public comments; however, this provision has been modified for the final rule (see next section for details).

c. 20 Percent Increase in DRG Rates for COVID–19 Patients

1. Provisions of the IFR

The IFR temporarily adopted the Medicare Hospital Inpatient Prospective Payment Add-On Payment for COVID–19 patients during the COVID–19 PHE period. The add-on payment for COVID–19 patients increased the weighting factor that would otherwise apply to the DRG to which the discharge is assigned by 20 percent.

2. Analysis of Public Comments

We received one comment regarding this provision of the IFR. The commenter noted that sole community hospitals (SCHs) are not subject to reimbursement under the DRG system and, as such, would not be eligible for the 20 percent increased reimbursement rate in the IFR. The commenter requested TRICARE modify reimbursement for SCHs to make them eligible for the 20 percent increased payment.

We appreciate the feedback from the commenter regarding a 20 percent increase for acute inpatient reimbursement for SCHs treating COVID–19 patients. We would note that while SCHs are not eligible for the 20 percent increased DRG reimbursement, we do an aggregate comparison of SCH claims paid with what we would have paid under the DRG methodology (which would include the 20 percent DRG increase) and if the SCH payments are lower than what would have been paid under the DRG methodology, we then pay the SCH the difference. So, while we are not adding 20 percent to the SCH calculation, it is added to the DRG and then used in the annual adjustment payment calculation.

3. Provisions of Final Rule

The final rule is consistent with the IFR.

d. LTCH Reimbursement at the Federal Rate

1. Provisions of the IFR

The IFR adopted the Medicare waiver of site neutral payment provisions for LTCHs during the COVID–19 PHE period, waiving the site neutral payment provisions and reimbursing all LTCH cases at the LTCH PPS standard Federal rate for claims within the COVID–19 PHE period.

2. Analysis of Public Comments

No public comments were received on this provision.

3. Provisions of Final Rule

The final rule is consistent with the IFR.

e. Adoption of Medicare's NTAPs for New Medical Services

1. Provisions of the IFR

The IFR permanently added coverage of Medicare's NTAP payments for new medical services, adding an additional payment to the DRG payment for new and emerging technologies approved by Medicare.

2. Analysis of Public Comments

No public comments were received on this provision.

3. Provisions of Final Rule

No changes were made in response to public comments; however, this provision has been revised in the final rule (see next section for details).

f. Adoption of Medicare's HVBP Program

1. Provisions of the IFR

The IFR permanently added coverage of Medicare's HVBP Program. The HVBP Program provides incentives to hospitals that show improvement in areas of health care delivery, process improvement, and increased patient satisfaction.

2. Analysis of Public Comments

No comments were received on this provision.

3. Provisions of Final Rule

The final rule content is consistent with the IFR content; however the HVBP provision has been moved from 199.14(a)(1)(iii)(E)(*6*) to 199.14(a)(1)(iv)(B) to account for the changes to the NTAP provisions.

IV. Summary of Changes From IFRs

A. Telephonic Office Visits

Telephonic office visits temporarily adopted in the IFR are permanently adopted in this final rule. The Director, DHA shall issue subsequent policy guidance of medically necessary and appropriate telephonic office visits to ensure best practices and protect against fraud.

B. Temporary Hospitals

The final rule modifies the waiver of acute care hospital requirements at paragraph 199.6(b)(4)(i) by expanding the waiver to include any facility registered with Medicare under its Hospitals Without Walls initiative, not just temporary hospitals and freestanding ASCs as were authorized by the IFR.

C. NTAPs

This final rule permanently adopts the Medicare NTAP methodology and future NTAP modifications published by CMS, for those otherwise approved benefits under the TRICARE Program. This rule also creates a pediatric NTAP reimbursement methodology based on 100 percent of the costs in excess of the MS–DRG. Finally, this rule provides a mechanism to establish a TRICARE-specific NTAP for those high-cost treatments that do not have an NTAP designation because the population affected and treated by these new technologies are outside of Medicare's beneficiary population.

D. Adoption of Medicare's HVBP Program

This final rule moves the HVBP provision from 32 CFR 199.14(a)(1)(iii)(E)(*6*) to 32 CFR

199.14(a)(1)(iv)(B) to account for the changes to the NTAP provisions; there are no changes to the content of the HVBP provision.

E. Telehealth Cost-Share/Copayment Waiver

This final rule finalizes the cost-share/copayment waiver provision as written in the IFR, except that it now terminates on the effective date of this rule, or the date of termination of the President's national emergency for COVID–19, whichever is earlier.

V. 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, distribute 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 (OMB) 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(g)(52) in this FR will revise the regulatory exclusion prohibiting coverage of telephone services and thereby allow permanent coverage of medical necessary and appropriate telephonic office visits for all TRICARE beneficiaries in all geographic locations.

The modification to paragraph 199.6(b)(4)(i) in this FR will allow any entity that temporarily enrolled with Medicare as a hospital through the Hospitals Without Walls initiative to be deemed to meet the requirements for acute care hospitals established under TRICARE for the duration of the COVID–19 pandemic. This will allow more entities to provide inpatient and outpatient hospital services, increasing access to medically necessary care for beneficiaries.

The modifications to paragraph 199.14(a)(1)(iv)(A) (previously 199.14(a)(1)(iii)(E)(*5*) in the IFR and re-designated in this final rule) will: (1) Adopt the Medicare NTAP methodology and future NTAP modifications published by CMS, (2) create a pediatric NTAP reimbursement methodology based on 100 percent of the costs in excess of the MS–DRG, and (3) provide a mechanism to reimburse high-cost treatments that do not have a Medicare NTAP designation (due to beneficiary population differences).

The modifications to paragraph 199.17(l)(3) in this rule will provide for an earlier termination of the temporary waiver of cost-sharing and copayments for telehealth.

c. Affected Population

The modifications in this rule impact all TRICARE beneficiaries, TRICARE-authorized providers, the TRICARE program staff and contractors. Beneficiaries will be impacted by the permanent addition of telephonic office visits, the elimination of the telehealth cost-share/copayment waivers, increased access to new technologies afforded by the pediatric NTAPs reimbursement methodology, and increased access to acute care in temporary hospitals. TRICARE-authorized providers will be minimally impacted in that telephonic office visit will give them a new means to provide care and treatment to beneficiaries and generate revenue. TRICARE-authorized providers who administer Medicare approved NTAPs to pediatric patients will be reimbursed at a higher rate. Acute care facilities that qualify under Medicare's Hospitals Without Walls initiative will benefit by automatically qualifying as a TRICARE-authorized provider for the duration of the pandemic. TRICARE program staff and contractors who administer the TRICARE benefit will be minimally impacted as this change will require them to update their systems to accommodate the change.

d. Costs [5]

The new incremental costs associated with this final rule are $20.88M through FY24, not including savings resulting from early termination of the telehealth cost-share/copayment waiver (approximately $4.8M savings per month). For context, this section also provides updated cost estimates for temporary benefit and reimbursement changes implemented in prior IFRs that are finalized in this FR ($278.0M through September 30, 2022), including the telehealth cost-share/copayment waiver being terminated by the FR (estimated cost $149.7M through September 30, 2022), and updated cost estimates associated with permanent reimbursement changes implemented in prior IFRs that are finalized in this FR ($13.0M through FY24). Administrative costs to implement all provisions are $0.67M in one-time costs for both previously implemented provisions and modifications in this final rule.

This estimate assumes the President's national emergency for COVID–19 would expire by September 2022. The number and severity of COVID–19 cases for TRICARE patients, along with the length of the President's declared national emergency for COVID–19 and the associated HHS PHE would impact the estimates provided in this section.

1. New Incremental Costs

The incremental health care impact of new permanent benefit and reimbursement changes implemented in the final rule is $20.88M through FY24, and includes coverage of telephonic office visits, expanded coverage of temporary hospitals, the reimbursement methodology for pediatric NTAP cases, and the addition of TRICARE NTAPs. These amounts are the only new costs associated with the FR (*i.e.,* costs for benefits and reimbursement changes that have not already been implemented).

TABLE 1—NEW COSTS DUE TO MODIFICATIONS IN THE FINAL RULE

Provision	Through FY2024
Paragraph 199.4(g)(52)—Permanent Coverage of Telephonic Office Visits	$19.6M
Paragraph 199.6(b)(4)(i)—Expanded Coverage for Temporary Hospitals	0M
Paragraph 199.14(a)(1)(iv)(A)(*2*)—Methodology for Pediatric NTAPs Cases	0.04M

[5] Most costs associated with this final rule are technically considered to be transfers, *i.e.,* an income transfer between taxpayers and program beneficiaries. The only true ''costs'' of this rule are administrative costs, and all other costs should be considered to be transfer payments.

TABLE 1—NEW COSTS DUE TO MODIFICATIONS IN THE FINAL RULE—Continued

Provision	Through FY2024
Paragraph 199.14(a)(1)(iv)(A)(*3*)—Addition of TRICARE NTAPs	1.2M
Total	20.88M

Telephonic Office Visits. Government expenditures for TRICARE first-pay and second pay claims for identifiable telephonic office visits amounted to approximately $7.6 million in Fiscal Year (FY) 2020 and $15.4 million in FY21. Also, the average government cost per service for telephonic office visits was $56, which is 19 percent less than the overall telehealth average of $81. This estimate assumes telephonic office visits will decrease after the pandemic, as beneficiaries become more comfortable or even prefer in-person visits. Additionally, the elimination of the telehealth cost-share/copayment waiver may shift some visits that could have been performed virtually to in-person as there will no longer be a financial incentive to obtain services virtually. After the drop in visits following the pandemic, we assume a modest (5 percent) increase in cost for telephonic office visits each subsequent FY. Lastly, as this provision was originally set to expire upon the expiration of the national emergency, and this estimate assumes that the national emergency declaration will terminate September 30, 2022, the incremental costs of this provision include only the costs in FY23 and FY24.

Expanded Coverage of Temporary Hospitals. This estimate assumes that care received at facilities that register with Medicare as hospitals would have been provided in other TRICARE-authorized hospitals but for the regulation change. We do not anticipate any induced demand for hospital care due to the authorization of new facilities. As such, there are no incremental costs associated with expanding coverage of temporary hospitals.

NTAP Pediatric Reimbursement Methodology. An analysis of claims data for FY20 and FY21 found 23 pediatric cases which would have qualified under this methodology. This estimate is based on an average of what would have been paid for those cases, along with calculations for increases in health care costs each year. This estimate includes only the difference between the standard NTAP rate (65 percent of the cost of treatment) and the NTAP Pediatric reimbursement rate (100 percent). This estimate is highly uncertain as the number of pediatric patients receiving an NTAP each year will vary (we assumed 15 cases or fewer per year), the costs of those NTAPs are unknown, and because the number of NTAPs approved by Medicare increases each year.

TRICARE NTAP Approval Process and Reimbursement Methodology. The costs of this provision were estimated by identifying one drug without a Medicare NTAP due to their use by the 64 and younger population, calculating the treatment costs for that drug, applying the TRICARE NTAP adjustment methodology, and identifying how many TRICARE beneficiaries were treated with that drug each year. This estimate is highly uncertain and is dependent on the number of TRICARE NTAPs approved each year by the Director, DHA, the cost of each of those technologies, and the number of TRICARE beneficiaries receiving each technology.

2. Costs Associated With Previously-Implemented Temporary Regulatory Provisions

Provisions under this portion of the estimate have already been implemented; cost estimates provided here are updates from estimates published in the associated IFR under which they were implemented. These amounts are estimated through the end of September 2022, when we assume the President's national emergency and the HHS PHE will end. An earlier or later termination of the national emergency or HHS PHE will impact the estimates for this portion of the final rule.

TABLE 2—COSTS DUE TO TEMPORARY PROVISIONS IMPLEMENTED IN PRIOR IFRS

Provision	Through September 30, 2022 (million)	Implementation date	Planned expiration
Paragraph 199.4(b)(3)(xiv)—SNF Three-Day Prior Stay Waiver.	$1.9	March 1, 2020	Termination of President's national emergency for COVID–19.
Paragraph 199.4(g)(52)—Temporary Waiver of the Exclusion on Audio-only Telehealth.	32.1	May 12, 2020	Termination of President's national emergency for COVID–19.
Paragraph 199.6(b)(4)(i)—Temporary Hospitals and Freestanding ASCs Registering as Hospitals (as implemented in the IFR).	0	September 3, 2020	Expiration of Medicare's Hospitals Without Walls Initiative.
Paragraph 199.6(c)(2) Waiver of provider licensing requirements for interstate and international practice.	0	May 12, 2020	Termination of President's national emergency for COVID–19.
Paragraph 199.14(a)(1)(iii)(E)(*2*)—20 Percent DRG Increase for COVID–19 Patients.	76.5	January 27, 2020	Termination HHS PHE.
Paragraph 199.14(a)(9)—LTCH Site Neutral Payments	17.8	January 27, 2020	Termination HHS PHE.
Paragraph 199.17(l)(3) Temporary Telehealth Cost-Share/Copayment Waiver.	149.7	May 12, 2020	Effective date of this final rule or termination of President's national emergency for COVID–19, whichever is earlier.
Total	278.0		

SNF Three-Day Prior Stay Waiver. The nominal cost associated with this provision is due to an assumption that, as a result of the waiver, SNF admissions will increase by three percent. This estimate is consistent with the estimate in the IFR.

Temporary Waiver of the Exclusion of Audio-only Telehealth Visits. This estimate accounts for amounts related to the temporary waiver of the exclusion of audio-only telehealth visits from the first IFR, and is consistent with the factors discussed above for telephonic office visits. Included are amounts for FY20 through the end of FY22. These amounts reflect the costs had the ASD(HA) not made telephonic office visits permanent, but continued to let them expire at the end of the national emergency. If the President's national emergency expires prior to the end of September 2022, these amounts will shift to the above permanent coverage of telephonic office visits.

Temporary Hospitals and Freestanding ASCs. 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. This estimate is consistent with the estimate in the IFR.

Waiver of Interstate and International Licensing for Providers. The zero cost estimate assumes patients who are seeing providers under relaxed licensing requirements would have either seen a different provider or the same provider in a different setting (*i.e.,* in-person as opposed to via telehealth) were it not for the waiver. This estimate is consistent with the estimate in the IFR.

20 Percent DRG Increase. In the second IFR, we estimated that in an eighteen-month period, we would spend $37.1M to 51.4M on the 20 percent DRG increase. Actual spending through the end of FY21 was $41.5M, consistent with and on the low end of that estimate. This is primarily due to a lower average hospitalization cost for COVID–19 patients. This estimate extends actual costs through the end of September 30, 2022. Additional costs would be incurred beyond that date if the HHS PHE continues to be in effect. This estimate is consistent with the lower end of the estimate in the IFR.

LTCH Site Neutral Payments. TRICARE is in the process of phasing in Medicare's site-neutral payment rates. The phase-in has been halted as a result of the IFR; this estimate assumes TRICARE LTCH claims will be paid at the full LTCH PPS rate through the end of the HHS PHE. This estimate is consistent with the estimate in the IFR.

Temporary Waiver of Cost-Shares and Copayments for Telehealth Services. The largest cost-driver for provisions in the previously published IFRs is the temporary waiver of cost-shares and copayments for telehealth, which is expected to cost $149.7M from implementation on May 12, 2020, through September 30, 2022. These costs are associated with the benefit as implemented in the previous IFR; because we are terminating the benefit early in the final rule, we expect to realize a cost savings of approximately $4.8M per month prior to the end of the President's national emergency for COVID–19. The IFR only estimated a 9-month cost ($66M). The estimate in this IFR is largely consistent with the original estimate (approximately $7.3M per month), with an expected decrease in per-month spend further from the initial days of the pandemic and the stay-at-home orders that prompted this provision.

3. Costs Associated With Previously-Implemented Permanent Regulatory Provisions

The second COVID–19 IFR implemented two permanent provisions, NTAPs and HVBP. Both are finalized in this FR. The costs associated with the changes to NTAPs implemented in this FR are provided in the first section of the cost estimate. This section provides costs associated with NTAPs as implemented in the IFR, as well as costs associated with the HVBP Program.

TABLE 3—COSTS DUE TO PERMANENT REIMBURSEMENT CHANGES IMPLEMENTED IN THE SECOND IFR

Provision	Through FY2024
Paragraph 199.14(a)(1)(iv)(A)—NTAPs (not including the new pediatric reimbursement methodology provided in table 1)	$9.1M
Paragraph 199.14(a)(1)(iv)(B)—HVBP Program	3.9M
Total	13.0M

NTAPs. The IFR included the cost estimate through September 30, 2021 (a range of $5.7M to $11.6M), while this estimate provides an updated five-year costing using actual TRICARE claims data for utilization and reimbursement of NTAPS. In creating this estimate, we identified TRICARE claims containing a treatment with a Medicare NTAP in either FY2020 or FY2021 and identified the total estimated add-on payment amounts and the total estimated Medicare cases each year, as published in the **Federal Register**. In FY2020, there were 18 treatments with NTAPs and 78 TRICARE claims containing one of these treatments; in FY2021, there were 23 NTAP treatments and 145 TRICARE claims with NTAPs, although the average NTAP maximum add-on amount decreased dramatically from FY2020 to FY2021 due to the average costs of the respective treatments.

For FY2022, there are a total of 38 Medicare treatments with NTAPs, 15 of which are new and represent a new traditional technology, Qualified Infectious Disease Products, or breakthrough technology. Consistent with the IFR, this estimate assumes TRICARE NTAPs would continue to 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 were being approved on a case-by-case basis by the Director, DHA, under waiver authority. In those cases, adopting NTAPs was likely to reflect a cost savings compared to the estimated costs, as waivers are typically paid at billed charges.

HVBP Program. The HVBP Program was implemented retroactive to January 1, 2020; we anticipated 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. This cost estimate is higher than the cost estimate published in the IFR ($2.5M), as there was more real-world data available to us on hospitals eligible for a positive adjustment for the initial implementation year.

e. Benefits

The addition of telephonic office visits as a permanent benefit will positively impact beneficiaries, particularly beneficiaries with limited access to broadband and other technology required for video telehealth visits, as this change will provide them better access to the existing telehealth benefit. This will result in avoided travel time and time spent in the provider's waiting room (a benefit of approximately one hour per beneficiary per visit, at a monetized value to the beneficiary of $20.00 per hour). Providers will benefit from telephonic office visits by being able to better treat their patients, particularly patients who might not come into the office for regular office visits. The implementation of a distinct pediatric reimbursement methodology for pediatric NTAPs will positively impact beneficiaries and providers, as providers will be able to offer beneficiaries access to new treatments knowing full reimbursement will be provided. Expansion of coverage of temporary hospitals will benefit beneficiaries, who will have access to more acute care facilities during the pandemic.

f. Alternatives

DoD considered several alternatives to this rulemaking. The first option considered not publishing a final rule or publishing a final rule finalizing the IFR provisions listed without any changes. The temporary changes would have expired as planned without modification. Under this option: Telephonic office visits would not have become a permanent benefit, the coverage of hospitals under Medicare's Hospitals Without Walls initiative benefit would have remained as published in the IFR (meaning facilities other than temporary hospitals and freestanding ambulatory surgical centers, such as freestanding emergency rooms, would have continued to be ineligible for temporary status as an acute care facility), a new pediatric reimbursement methodology for NTAPs would not have been implemented, and the temporary waiver of telehealth cost-shares and copayments would not have been potentially terminated early (at a potential cost of around $4.8M per month). Each of the modifications in this final rule addresses a concern or further develops the benefit based on information we have gathered since the IFRs were published. This option was determined to be insufficient to meet the needs of the TRICARE Program.

DoD also considered publishing this final rule as is, but restricting telephonic office visits to only those TRICARE beneficiaries without access to conventional two-way audio-video equipment. We determined such a restriction would be impractical, unnecessary, and difficult and costly to administer. This option would have been inconsistent with modern practices in the health care field and would have placed an unnecessary burden on providers and beneficiaries. This option was not selected because its benefits did not outweigh the administrative burden on DHA, providers, and the potential cost of reduced access on beneficiaries.

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

The Assistant Secretary of Defense for Health Affairs certifies that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

DoD anticipates that permanent coverage of telephonic office visits will impact approximately 133,000 individual professional providers. The provisions impacting inpatient facilities (the 20 percent DRG increase for COVID–19 patients, NTAPs, and the HVBP Program) will impact between 3,400 and 3,800 hospitals. The number of LTCHs impacted by site neutral payments will be between 200 and 300. 1,300 SNFs will be impacted by the three-day prior hospital stay waiver. We are unable to estimate the number of providers impacted by the interstate and international licensing waiver, but expect it will be fairly small as a percentage of total TRICARE providers. We are similarly unable to estimate how many facilities will be eligible as TRICARE-authorized acute care facilities by registering with Medicare's Hospitals Without Walls initiative who would not have been otherwise eligible under TRICARE, but expect this to be a small number as well.

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 TRICARE 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 and permanent 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 businesses. 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 telephonic office visits and temporary hospitals are not expected to result in any adverse economic impact on hospitals or other health care providers.

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 (UMRA) (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. This final rule 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 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. This final rule will not have a substantial effect on State and local governments.

G. Executive Order 13175, ''*Consultation and Coordination With Indian Tribal Governments*''

It has been determined that this rule does not have a substantial effect on Indian tribal governments. This rule does not impose substantial direct compliance costs on one or more Indian tribes, preempt tribal law, or effect the distribution of power and responsibilities between the federal government and Indian tribes.

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.

For the reasons stated in the preamble, the interim final rules amending 32 CFR part 199, which were published at 85 FR 27921–27927, May 12, 2020, and 85 FR 54914–54924, September 3, 2020, are adopted as final with changes, except for the note to paragraph 199.4(g)(15)(i)(A), published at 85 FR 54923, September 3, 2020, which remains interim, and DoD further amends 32 CFR part 199 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 § 199.2 by adding definitions for ''Biotelemetry,'' ''Telephonic consultations'' and ''Telephonic office visits'' in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

Biotelemetry. A diagnostic or monitoring procedure for the detection or measurement of human physiologic functions from a distance using a biotelemetry device to remotely monitor various vital signs of ambulatory patients. Biotelemetry may also be referred to as remote physiologic monitoring of physiologic parameters. See § 199.4.

* * * * *

Telephonic consultations: A covered consultation service conducted via telephone call between TRICARE-authorized providers, including a verbal and written report to the patient's treating/requesting physician or other TRICARE-authorized provider.

Telephonic office visits. A covered service provided via a telephone call between a beneficiary who is an established patient and a TRICARE-authorized provider. See § 199.4.

* * * * *

■ 3. Amend § 199.4 by revising paragraphs (c)(1)(iii), (g)(52) introductory text and (g)(52)(i) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(c) * * *

(1) * * *

(iii) *Telehealth services.* Health care services covered by TRICARE and provided through the use of telehealth modalities including telephone services for: telephonic office visits; telephonic consultations; electronic transmission of data or biotelemetry or remote physiologic monitoring services and supplies, are covered services to the same extent as if provided in person at the location of the patient if those services are medically necessary and appropriate for such modalities. The Director will establish special procedures for payment for such services. Additionally, where appropriate, in order to incentive the use of telehealth services, the Director may modify the otherwise applicable beneficiary cost-sharing requirements in paragraph (f) of this section which otherwise apply.

* * * * *

(g)(52) *Telephone services.* Services or advice rendered by telephone are excluded. Exceptions:

(i) Medically necessary and appropriate Telephonic office visits are covered as authorized in paragraph (c)(1)(iii) of this section.

* * * * *

■ 4. Effective June 1, 2022 amend § 199.6 by revising the note to 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, any entity that temporarily enrolls with Medicare as a hospital may be temporarily exempt from certain institutional requirements for acute care hospitals under TRICARE. To the extent practicable, the Director, Defense Health Agency (DHA), will adopt by administrative policy any process requirement related to Medicare's Hospitals Without Walls initiative.

* * * * *

■ 5. Amend § 199.14 by:

■ a. Adding a sentence at the end of paragraph (a)(1)(iii)(E) introductory text;

■ b. Adding paragraph (a)(1)(iv);

■ c. Redesignating paragraph (a)(1)(iii)(E)(*5*) as paragraph (a)(1)(iv)(A) and revising newly redesignated paragraph (a)(1)(iv)(A);

■ d. Redesignating paragraph (a)(1)(iii)(E)(*6*) as paragraph (a)(1)(iv)(B).

The revision and addition read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *

(1) * * *

(iii) * * *

(E) *** Additional adjustments to DRG amounts are included in paragraph (a)(1)(iv) of this section.

* * * * *

(iv) *Special Programs and Incentive Payments.* (A) *Additional payment for new medical services and technologies.* TRICARE will make New Technology Add On Payments (NTAPs) adjustments to DRGs as provided in paragraphs (a)(1)(iv)(A)(*1*) through (a)(1)(iv)(A)(*11*) of this section. 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.

(*1*) *Adoption of Medicare NTAPs.* For TRICARE covered services and supplies, TRICARE will adopt Medicare NTAPs as implemented under 42 CFR 412.87 under the same conditions as published by the Centers for Medicare & Medicaid Services, except for pediatric cases.

(*2*) *Pediatric cases.* For pediatric NTAP DRGs, the TRICARE NTAP adjustment shall be modified to be set at 100 percent of the costs in excess of the Medicare Severity-Diagnosis Related Group (MS–DRG) payment. As used in this paragraph, pediatric is defined as services and supplies provided to individuals under the age of 18, or who are being treated in a children's hospital or in a pediatric ward.

(*3*) *TRICARE designated NTAP adjustments.* For categories of TRICARE covered services and supplies for which Medicare has not established an NTAP adjustment for DRGs, the Director, DHA may designate a TRICARE NTAP adjustment through a process using criteria to identify and select such new technology services/supplies similar to that utilized by Medicare under 42 CFR 412.87. The Director, DHA may then designate a TRICARE NTAP reimbursement adjustment through a process using a methodology similar to the Medicare methodology outlined in 42 CFR 412.88. This discretionary authority to designate TRICARE NTAP adjustments shall apply to services and supplies typically provided to TRICARE beneficiaries age 64 or younger when Medicare has not established an NTAP adjustment for such services/supplies. As with other discretionary authority under this part, a decision to designate a TRICARE category of services/supplies for an NTAP adjustment to DRGs and the amount of such an adjustment are not subject to the appeal and hearing procedures of § 199.10. The Director, DHA, shall select which new technologies may be designated as TRICARE NTAPs and will publish this list based on the eligibility criteria and reimbursement methodology provided in paragraphs (a)(1)(iv)(A)(*4*) through (a)(1)(iv)(A)(*11*) of this section.

(*4*) *Eligibility requirements and reimbursement methodology for TRICARE designated NTAP adjustments.* A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of TRICARE beneficiaries. The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of TRICARE beneficiaries.

(*5*) *Criteria for improvement.* A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of TRICARE beneficiaries means one or more of the following:

(*i*) The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(*ii)* The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

(*iii*) The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following seven outcomes: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; A decreased rate of at least one subsequent diagnostic or therapeutic intervention; A decreased number of future hospitalizations or physician visits; A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; An improvement in one or more activities of daily living; An improved quality of life; or A demonstrated greater medication adherence or compliance.

(*iv*) The totality of the information otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of TRICARE beneficiaries.

(*6*) *Evidence.* Evidence from scientific literature may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of TRICARE beneficiaries.

(*7*) *Prevalence.* The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among TRICARE beneficiaries.

(*8*) *Subpopulation.* The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

(*9*) *Newness criteria.* A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology becomes available for DRG recalibration). After TRICARE has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

(*10*) *Payment methodology.* For discharges involving new medical services or technologies that meet the criteria specified in paragraphs (a)(1)(iv)(A)(*4*) through (a)(1)(iv)(A)(*9*) and that are approved as TRICARE NTAPs per paragraph (a)(1)(iv)(A)(*11*) of this section, TRICARE payment will be the lesser of:

(*i*) The CMS designated percentage of the estimated costs of the new technology or medical service, as published in 42 CFR 412.88; or

(*ii*) The CMS designated percentage of the difference between the full DRG payment and the hospital's estimated cost for the case, as published in 42 CFR 412.88.

(*11*) *Publication and timing.* TRICARE may consider whether a new medical service or technology meets the eligibility criteria specified in paragraphs (a)(1)(iv)(A)(*4*) through (a)(1)(iv)(A)(*9*) of this section and announce the results on the NTAP website. In doing so, TRICARE only considers, for add-on payments for a particular fiscal year, an application for which the new medical device or product has received FDA marketing authorization by July 1 prior to the particular fiscal year; or the application is submitted under an alternative pathway to the FDA for which conditional NTAP approval for FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

* * * * *

■ 6. Amend § 199.17 by adding a second sentence at the end of paragraph (l)(3)(iii) to read as follows:

§ 199.17 TRICARE program.

* * * * *

(l) * * *

(3) * * *

(iii) * * * This temporary waiver provision terminates July 1, 2022 or the date of termination of the President's declared national emergency for COVID–19, whichever is earlier.

* * * * *

Dated: May 12, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–10545 Filed 5–31–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0171]

RIN 1625–AA08

Special Local Regulation; Tampa Bay, St. Petersburg, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the existing special local regulations within the Seventh Coast Guard District Captain of the Port (COTP) St. Petersburg Zone by removing an event that no longer takes place, and by updating the location of an existing event. These changes are being made because one event sponsor halted the event for the forseeable future, and the other changed the event details.

DATES: This final rule is effective July 1, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2022–0171 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Marine Science Technician Second Class Regina L. Cuevas, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228–2191, email *Regina.L.Cuevas@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On March 29, 2022, the Coast Guard published a notice of proposed rulemaking (NPRM) in the **Federal Register** titled, ''Special Local Regulations; Recurring Marine Events, Sector St. Petersburg.'' [1] In the NPRM we stated the purpose of the rulemaking was to remove one existing recurring marine event that is no longer held and to change the location and date of an existing recurring marine event within the Seventh Coast Guard District Captain of the Port (COTP) St. Petersburg Zone that are listed in 33 CFR 100.703, Table 1 to § 100.703. With the postponement of one event for the forseeable future, and the change in date and location of another, the changes proposed in the NPRM were necessary to ensure that Table 1 to § 100.703 accurately reflected the events taking place within the COTP St. Petersburg Zone, and in the order the events occur. The NPRM invited comments on the proposed changes to Table 1 to § 100.703. During the comment period that ended April 28, 2022, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The COTP St. Petersburg has determined it necessary to revise the existing regulations in order to avoid confusion regarding the special local regulations (SLR) in the COTP St. Petersburg Zone.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published April 1, 2022.

This rule makes the following changes in 33 CFR 100.703:

1. Move the event listed in Table 1 to § 100.703, Line No. 5, ''Sarasota Powerboat Grand Prix/Powerboat P–1 USA, LLC to Line No. 4. We are not making any other changes to this event.

2. Move Table 1 to § 100.703, Line No. 4, to Line No. 5, and revise the event to reflect a name change, course location, and date and time for the event.

3. Delete the event listed in Table 1 to § 100.703, Line No. 6, ''Battle of the Bridges/Sarasota Scullers Youth Rowing Program.''

Marine events listed in Table 1 to § 100.703 are listed as recurring over a particular time, during each month and each year. Exact dates are intentionally omitted since calendar dates for specific events change from year to year. Once dates for a marine event are known, the Coast Guard notifies the public it intends to enforce the special local regulation through various means including a notice of enforcement published in the **Federal Register**, Local Notice to Mariners, and Broadcast Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the special local regulations. These areas are limited in size and duration, and usually do not affect high vessel traffic areas. Moreover, the Coast Guard will provide advance notice of the regulated areas to the local maritime community via Notice of Enforcement published in the **Federal Register**, by Local Notice to Mariners, Broadcast to Mariners via VHF–FM marine channel 16, and the rule will allow vessels to seek permission to enter the regulated area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 0 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement

[1] 87 FR 17957.