SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

This rule is needed to carry out the requirements of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget guidance M–23–05. The rule adjusts, as required for 2023, the maximum civil penalties under 29 CFR parts 4071 and 4302 that the Pension Benefit Guaranty Corporation (PBGC) may assess for failure to provide certain notices or other material information and certain multiemployer plan notices.

PBGC's legal authority for this action comes from the Federal Civil Penalties Inflation Adjustment Act of 1990 as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and from sections 4002(b)(3), 4071, and 4302 of the Employee Retirement Income Security Act of 1974 (ERISA).

Major Provisions of the Regulatory Action

This rule adjusts as required by law the maximum civil penalties that PBGC may assess under sections 4071 and 4302 of ERISA. The new maximum amounts are $2,586 for section 4071 penalties and $345 for section 4302 penalties.

Background

PBGC administers title IV of ERISA. Title IV has two provisions that authorize PBGC to assess civil monetary penalties.[1] Section 4302, added to ERISA by the Multiemployer Pension Plan Amendments Act of 1980, authorizes PBGC to assess a civil penalty of up to $100 a day for failure to provide a notice under subtitle E of title IV of ERISA (dealing with multiemployer plans). Section 4071, added to ERISA by the Omnibus Budget Reconciliation Act of 1987, authorizes PBGC to assess a civil penalty of up to $1,000 a day for failure to provide a notice or other material information under subtitles A, B, and C of title IV and sections 303(k)(4) and 306(g)(4) of title I of ERISA.

Adjustment of Civil Penalties

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,[2] which requires agencies to adjust civil monetary penalties for inflation and to publish the adjustments in the **Federal Register**. An initial adjustment was required to be made by interim final rule published by July 1, 2016, and effective by August 1, 2016. Subsequent adjustments must be published by January 15 each year after 2016.

On December 15, 2022, the Office of Management and Budget issued memorandum M–23–05 on implementation of the 2023 annual inflation adjustment pursuant to the 2015 act.[3] The memorandum provides agencies with the cost-of-living adjustment multiplier for 2023, which is based on the Consumer Price Index (CPI–U) for the month of October 2022, not seasonally adjusted. The multiplier for 2023 is 1.07745. The adjusted maximum amounts are $2,586 for section 4071 penalties and $345 for section 4302 penalties.

Compliance With Regulatory Requirements

The Office of Management and Budget has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866 and therefore not subject to its review.

The Office of Management and Budget also has determined that notice and public comment on this final rule are unnecessary because the adjustment of civil penalties implemented in the rule is required by law. See 5 U.S.C. 553(b).

Because no general notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4071

Penalties.

29 CFR Part 4302

Penalties.

In consideration of the foregoing, PBGC amends 29 CFR parts 4071 and 4302 as follows:

[1] Under the Federal Civil Penalties Inflation Adjustment Act of 1990, a penalty is a civil monetary penalty if (among other things) it is for a specific monetary amount or has a maximum amount specified by Federal law. Title IV also provides (in section 4007) for penalties for late payment of premiums, but those penalties are neither in a specified amount nor subject to a specified maximum amount.

[2] Sec. 701, Public Law 114–74, 129 Stat. 599–601 (Bipartisan Budget Act of 2015).

[3] See M–23–05, Implementation of Penalty Inflation Adjustments for 2023, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, *https://www.whitehouse.gov/wp-content/uploads/2022/12/M-23-05-CMP-CMP-Guidance.pdf.*

PART 4071—PENALTIES FOR FAILURE TO PROVIDE CERTAIN NOTICES OR OTHER MATERIAL INFORMATION

■ 1. The authority citation for part 4071 continues to read as follows:

Authority: 28 U.S.C. 2461 note, as amended by sec. 701, Pub. L. 114–74, 129 Stat. 599–601; 29 U.S.C. 1302(b)(3), 1371.

§ 4071.3 [Amended]

■ 2. In § 4071.3, remove the number ''$2,400'' and add in its place the number ''$2,586''.

PART 4302—PENALTIES FOR FAILURE TO PROVIDE CERTAIN MULTIEMPLOYER PLAN NOTICES

■ 3. The authority citation for part 4302 continues to read as follows:

Authority: 28 U.S.C. 2461 note, as amended by sec. 701, Pub. L. 114–74, 129 Stat. 599–601; 29 U.S.C. 1302(b)(3), 1452.

§ 4302.3 [Amended]

■ 4. In § 4302.3, remove the number ''$320'' and add its place the number ''$345''.

Issued in Washington, DC.

Gordon Hartogensis,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. 2023–00499 Filed 1–11–23; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DoD–2021–HA–0015]

RIN 0720–AB85

Expanding TRICARE Access to Care in Response to the COVID–19 Pandemic

AGENCY: Department of Defense.

ACTION: Interim final rule with request for comments.

SUMMARY: The Assistant Secretary of Defense for Health Affairs (ASD(HA)) issues this interim final rule (IFR) with comment to modify the TRICARE regulation by adding freestanding End Stage Renal Disease (ESRD) facilities as a category of TRICARE-authorized institutional provider and establishing reimbursement for such facilities and by temporarily adopting Medicare's New Coronavirus Disease 2019 (COVID–19) Treatments Add-on Payments (NCTAPs).

DATES:

Effective date: This IFR with comment is effective on January 12, 2023 through the end of the declared public health emergency (PHE), including any extensions, (as determined by 42 United States Code (U.S.C.) 247d), except the changes to ESRD facility provider status and reimbursement are permanent and will not expire. The ASD(HA) will publish a document announcing the expiration date for the temporarily adopted Medicare NCTAPs consistent with information in the **SUPPLEMENTARY INFORMATION** section.

Applicability date: Changes to ESRD provider status and facility reimbursement and the NCTAP provisions are applicable for TRICARE covered services received on or after the effective date of this IFR.

Comment date: Comments are invited and must be submitted on or before March 13, 2023.

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

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, Regulatory Directorate, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

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

- Jahanbakhsh Badshah, Defense Health Agency, Medical Benefits and Reimbursement Section, 303–676–3881, *Jahanbakhsh.Badshah.civ@health.mil,* or Jennifer Stankovic, Defense Health Agency, Medical Benefits and Reimbursement Section, 303–676–3742, *Jennifer.L.Stankovic.civ@health.mil,* for issues related to freestanding End Stage Renal Disease facilities.
- Sharon Seelmeyer, Defense Health Agency, Medical Benefits and Reimbursement Section, 303–676–3690, *Sharon.l.seelmeyer.civ@health.mil,* for issues related to NCTAPs.

SUPPLEMENTARY INFORMATION: *Expiration date:* Unless extended after consideration of submitted comments, the provision adopting Medicare NCTAPs will expire the last day of the fiscal year (FY) in which the Secretary of the Department of Health and Human Services (HHS) terminates the COVID–19 PHE. The adoption of ESRD facilities as a type of TRICARE-authorized institutional provider and the changes to the reimbursement of such facilities are permanent and will not expire.

The ASD(HA) will publish a document in the **Federal Register** announcing the expiration date, as appropriate, and will publish a Final Rule with any modifications made after consideration of public comments, the impact of the provisions in this IFR, and changes in the state of the COVID–19 pandemic.

I. Executive Summary

A. Purpose of the Rule

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named ''SARS–CoV–2,'' and the disease it causes is referred to as COVID–19. On January 31, 2020, the Secretary of HHS determined that a PHE had existed since January 27, 2020. On March 13, 2020, the President declared a national emergency due to the COVID–19 outbreak, retroactive to March 1, 2020 (Proclamation 9994, 85 FR 15337). The current administration has continued the national emergency declaration, via a notice issued February 18, 2022, which was published in the **Federal Register** on February 23, 2022 (87 FR 10289). Following the declaration of the national emergency, the President signed into law multiple statutes to provide economic and health care relief for individuals and businesses, including health care providers.

While the substantial access to COVID–19 vaccinations in the United States initially resulted in State and local governments relaxing restrictions for individuals and in improved conditions for health care providers due to the decreasing rate of new COVID–19 cases, the emergence of the Delta variant of the virus, which proved to be more infectious and more resistant to vaccination, resulted in a surge of COVID–19 infections in the United States, as well as an increase in the rate of hospitalizations, deaths, and health care providers at capacity. In July 2021, the Centers for Disease Control and Prevention (CDC) released guidance recommending that both vaccinated and unvaccinated individuals wear face masks in public indoor settings in areas of substantial or high transmission. Likewise, the Federal Government and many State, local, and tribal governments resumed or increased various restrictions. In December 2021, the Omicron variant replaced the Delta variant as the predominant COVID–19 variant in the United States. Although the Omicron variant is reportedly less severe than previous variants, it also results in a much higher level of transmission than previous variants and is still responsible for high levels of severe illness, hospitalization, and death, primarily in the unvaccinated and immunocompromised populations. Additionally, COVID–19 vaccines available in the United States are currently less effective at preventing COVID–19 caused by the Omicron variant. The CDC also states that new variants of COVID–19 are expected to occur, and that even if a variant is less severe in general, ''an increase in the overall number of cases could cause an increase in hospitalizations, put more strain on healthcare resources and potentially lead to more deaths.'' [1] Thus, the pandemic continues to threaten to strain the health care system. Although most States have again relaxed restrictions, due to the continuation of pandemic conditions—namely the continuing rates of new cases; hospitalizations; deaths; providers rationing health care resources; and intensive care units at or beyond capacity—the President has continued the national emergency declaration.

Consistent with the President's national emergency declaration and as a result of the COVID–19 pandemic, the ASD(HA) hereby modifies the following regulations, but in each case, only to the extent determined necessary to ensure that TRICARE beneficiaries have expanded access to care required for the treatment of COVID–19 and for other medically necessary care, and that TRICARE continues to reimburse like Medicare, to the extent practicable, as required by 10 U.S.C. 1079(i).

Freestanding ESRD Facilities 32 CFR 199.6(b)(4)(xxi) and 199.14(c): These provisions establish freestanding ESRD facilities as institutional providers within the TRICARE program and establish a TRICARE reimbursement methodology for freestanding ESRD facilities. Currently these facilities are classified as Corporate Service Providers (CSPs) and are reimbursed using a fee-for-service (FFS) methodology for covered professional services, and may not be paid institutional charges (*e.g.,* reimbursement for general nursing services or the use of treatment rooms).

[1] *https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html?s_cid=11723:covid%2019%20variants%20of%20concern:sem.ga:p:RG:GM:gen:PTN:FY22.*

The inclusion of freestanding ESRD facilities as institutional providers is required first in order to permit TRICARE reimbursement of institutional charges. Both changes (making these providers authorized institutional providers and adding a reimbursement methodology) will make TRICARE reimbursement of freestanding ESRD facilities, as well as dialysis services and supplies, more consistent with the Medicare reimbursement methodology for freestanding ESRD facilities, in accordance with the statutory requirement in 10 U.S.C. 1079(i) to reimburse like Medicare for like services and supplies provided by an authorized TRICARE institutional provider when determined to be practicable as required. These permanent changes are included in this IFR because existing restrictions on ESRD facilities (*i.e.*, provider status and professional services only-based reimbursement) reduce access to medically necessary, often lifesaving services for immunocompromised ESRD patients. This is of even greater concern during the COVID–19 pandemic, especially with the emergence of the Delta variant, which is more severe and more resistant to vaccination in immunocompromised individuals (*i.e.,* those with ESRD), and the Omicron variant, which is much more resistant to vaccination and much more transmissible than previous variants.

DRG Add-on for NCTAP 32 CFR 199.14(a)(1)(iv)(C): This change temporarily adopts Medicare's NCTAP under the Inpatient Prospective Payment System (IPPS) for COVID–19 cases that meet Medicare's criteria. By statute, 10 U.S.C. 1079(i), TRICARE shall, to the extent practicable, reimburse institutional providers in accordance with Medicare reimbursement rules. As such, TRICARE has generally adopted the Medicare IPPS using the Diagnosis-Related Group (DRG) system (32 CFR 199.14(a)(1)). Based on Section 3710 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), Medicare increased the weighting factor of the assigned DRG by 20 percent for an individual diagnosed with COVID–19 discharged during the COVID–19 PHE period. On November 6, 2020 (effective November 2, 2020), the Centers for Medicare and Medicaid Services (CMS) issued an IFR (85 FR 71142), further increasing the current IPPS payment amounts as drugs and biological products become available and are authorized or approved by the Food and Drug Administration for the treatment of COVID–19 in the inpatient setting for the duration of the PHE. In a final rule (86 FR 44774), CMS subsequently extended the NCTAP expiration date to the end of the FY in which the PHE ends for all eligible products, with any new technology add-on payment reducing the NCTAP amount. CMS stated that they pursued this change because they ''anticipate that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned Medicare Severity-DRG may not adequately reflect the additional cost of new COVID–19 treatments'' and they wish to ''continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE.'' In issuing a final rule, the DoD may make modifications based on public comments received, the impact of the provisions in this IFR, and any changes in the conditions surrounding the pandemic.

B. Interim Final Rule Justification

Agency rulemaking is governed by the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* Section 553(b) requires that, unless the rule falls within one of the enumerated exemptions, DoD must publish a notice of proposed rulemaking in the **Federal Register** that provides interested persons an opportunity to submit written data, views, or arguments prior to finalization of regulatory requirements. Section 553(b)(B) authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement when the agency, for ''good cause,'' finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. For both the NCTAP and ESRD provisions, the ASD(HA) has determined notice and public comment before promulgation of this rule would be contrary to the public interest and therefore finds good cause to enact the changes described in this rule through an IFR, effective the date of publication in the **Federal Register**. The ASD(HA)'s justification is as follows:

First, as of this rule's writing, both the PHE and the President's declared national emergency are still in effect; therefore, the Administration still finds COVID–19 to be an emergency situation and unnecessary delays should be avoided to the greatest extent possible. While DoD acknowledges that the pandemic has been ongoing for many months, DoD maintains that, given the ongoing uncertainty as to what dangers future COVID–19 variants may pose, it is impracticable and contrary to the public interest to delay these regulations until a full public notice-and-comment process is completed. Second, patients and providers alike continue to struggle due to burdens imposed by the COVID–19 pandemic. The emergence of the Delta and Omicron variants have resulted in increased COVID–19 cases, hospitalizations, and deaths, which have worsened resource constraints on providers, limited access to medically necessary health care services and supplies for TRICARE beneficiaries, and cost many beneficiaries their health and their lives. Meanwhile, the trajectory of COVID–19, including number of future variants and severity of each variant, remains an unknown variable. In such a precarious and uncertain healthcare landscape, it is imperative that TRICARE ensure continued access to care for TRICARE beneficiaries while simultaneously following its statutory mandate to pay for like services and supplies using Medicare reimbursement methodologies, when practicable. In promulgating this IFR, the Defense Health Agency (DHA) has evaluated and re-evaluated each provision to ensure the IFR remains up to date with current developments during the COVID–19 pandemic and to publish only such requirements and authorities that DHA deems necessary to respond to the declared national emergency and PHE in order to best provide for the health of TRICARE beneficiaries. It is likewise crucial that TRICARE authorize ESRD facilities as institutional providers as expeditiously as possible to ameliorate the resource constraints current TRICARE-authorized providers are facing and increase the access of beneficiaries with a life-threatening disease to proven, medically necessary care in the most appropriate setting. Considerations specific to the two provisions contained in this IFR are discussed in greater depth below. Finally, this rule imposes no restrictions, financial penalties, or regulatory burdens on the public that would make a notice and comment period necessary or prudent; in fact, this IFR would ensure better access to medically necessary care for TRICARE beneficiaries by providing appropriate reimbursement to TRICARE providers. We anticipate no negative feedback from the general public on the provisions within this IFR; advance notice and comment would only delay increased payment to providers and improved access to care for beneficiaries. Moreover, an earlier DHA COVID–19 IFR (85 FR 54914–54924) that relaxed

certain regulatory restrictions for providers and increased reimbursement to providers in order to follow Medicare reimbursement methodologies received no negative comments. A delay to wait for a notice and comment period is therefore impracticable and is contrary to public interest and public health. Further, the public is still encouraged to comment on this IFR and DHA is committed to responding to any comments in a future final rule.

Specifically regarding the adoption of Medicare's NCTAPs, it is crucial that providers be reimbursed adequately for COVID–19 treatments involving new, high-cost services and supplies to which Medicare has deemed appropriate to apply an add-on payment. Adopting this change will ensure that TRICARE beneficiaries continue to receive maximized access to new, high-cost COVID–19 treatments such as remdesivir and convalescent plasma as well as any qualifying treatments that may follow. CMS established the NCTAP ''to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE'' in an IFR (85 FR 71142) published November 6, 2020. Due to the statutory requirement that TRICARE reimburse providers using Medicare reimbursement methodologies for like services and supplies, when practicable, DHA adopted these changes, as well as the changes made in this IFR, because the ASD(HA) determined that such changes were practicable and necessary due to the COVID–19 pandemic. Although DHA is not required to adopt all Medicare reimbursement methodologies—only those that are practicable—the ASD(HA) does find it practicable to adopt Medicare's NCTAP and likewise finds it necessary to promulgate this change in an IFR, effective the publication date of this IFR (*i.e.* dispensing with prior notice and opportunity for public comment due to good cause), for the reasons discussed in this section and throughout this preamble. By not matching Medicare reimbursement as anticipated under statutory requirements and after DHA has previously adopted Medicare reimbursement changes specific to the PHE, providers may be hesitant to take on TRICARE beneficiaries as patients, especially while they continue to struggle financially. Such a scenario could occur during the remainder of the COVID–19 PHE if provider resource constraints continue or worsen or another variant surges. DoD wishes to avoid any such scenario which could impede TRICARE beneficiary future access to care and which may also decrease beneficiary satisfaction, decrease beneficiary outcomes, and negatively impact active duty service member readiness.

Additional good cause exists to publish as an IFR the permanent amendments to the TRICARE regulation regarding adoption of freestanding ESRD facilities as authorized institutional providers and modifications to the reimbursement of freestanding ESRD facilities. As previously noted, TRICARE is mandated by law, 10 U.S.C. 1079(i)(2), to reimburse institutional providers using the Medicare reimbursement methodologies, to the extent practicable. Medicare recognizes freestanding and hospital-based ESRD facilities as institutional providers and reimburses ESRD facilities using a specific ESRD Prospective Payment System (PPS). Due to historically low volume, TRICARE has neither classified freestanding ESRD facilities as institutional providers nor adopted the Medicare ESRD PPS. However, in recent years, there has been increasing volume of TRICARE beneficiaries requiring ESRD services and DHA has determined that because the TRICARE payment methodology for freestanding ESRD facilities designated as CSPs does not reimburse these facilities for their institutional charges, this could result in freestanding ESRD providers declining to accept TRICARE patients who need dialysis and other ESRD services and supplies. As such, the ASD(HA) has determined that, while it would be impracticable to adopt the Medicare ESRD PPS, it is practicable to adopt a TRICARE-specific ESRD rate that approximates the Medicare ESRD rate. The national emergency caused by the COVID–19 pandemic and extended by the Delta, Omicron, and potentially other future variants has resulted in a severe shortage of health care providers and supplies, and it is imperative that (1) TRICARE beneficiaries have maximized access to care for ESRD services and (2) ESRD services are available, where appropriate, outside hospital settings to ensure that hospitals are more efficiently able to maximize resources to treat COVID–19 and other conditions requiring the acuity of inpatient or outpatient hospital settings. Due to these resource constraints for providers and the lack of reimbursement for institutional charges under the TRICARE program's existing reimbursement methodology based on restricted TRICARE provider status, ESRD facilities have notified DHA that they may be forced to leave the TRICARE private sector network if payment rates do not include reimbursement for institutional charges. A reduction in network ESRD facilities would severely restrict the access of TRICARE beneficiaries to life-saving ESRD services and supplies during the remainder of the COVID–19 pandemic and could impose additional, unnecessary costs on TRICARE beneficiaries who consequently have to choose care from a provider who is out of network or is not a participating provider within the TRICARE program. Barriers to access and increased costs could prevent TRICARE beneficiaries from seeking or receiving medically necessary treatment for ESRD. Furthermore, ESRD is a life-threatening condition and patients with ESRD are immunocompromised—and therefore more susceptible to COVID–19–so it is especially imperative during the COVID–19 pandemic that these beneficiaries receive prompt, accessible, high-quality ESRD services in the most appropriate setting. Having patients with ESRD receive treatment in an ESRD facility rather than in another setting may also improve capacity or other resource constraints that other institutional providers are facing during the COVID–19 pandemic; by not treating ESRD patients, these providers will be able to focus their resources on treating other patients, such as those with COVID–19 during times of surging infection rates or new variants. For example, should hospitals continue to experience periodic patient admission surges, TRICARE beneficiaries who are ESRD patients would neither be occupying valuable emergency department and inpatient beds nor would they be turned away from treatment due to hospitals being over capacity, as they could be treated in freestanding ESRD facilities instead of in a hospital setting (as appropriate for their specific medical needs). Lastly, DoD intends to make this change in ESRD provider status and reimbursement methodology permanent, in conformance with statutory mandates to reimburse providers of services of the same type (*i.e.*, institutional providers) to the extent practicable in accordance with Medicare reimbursement methodologies. While ensuring adequate access to ESRD providers by immunocompromised TRICARE ESRD patients during the COVID–19 national emergency, it would not be practicable or efficient to revoke the new provider status and fail to continue reimbursing ESRD providers to the extent practicable in accordance with Medicare

reimbursement upon the expiration of the President's national emergency declaration.

In exercising the authority under statute 5 U.S.C. 553(b)(B), the ASD(HA) has determined that good cause exists to avoid delay as further notice and public comment would be impracticable and contrary to the public interest. Nonetheless, public comments on this IFR are still invited and DoD is committed to considering all comments in enacting any final regulations. Therefore, pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated in this preamble, the ASD(HA) concludes that there is good cause to dispense with prior public notice and the opportunity to comment on this rule before finalizing this rule. For the same reasons and due to the fact that no harm could occur in implementing this rule effective upon publication, as it does not impose any burdens upon the public but rather increases their reimbursement, the ASD(HA) has determined, consistent with section 553(d) of the APA, that there is good cause to make this IFR effective immediately upon publication in the **Federal Register**.

C. Summary of Major Provisions

Freestanding ESRD Facilities

These provisions, 32 CFR 199.6 and 199.14, establish freestanding ESRD facilities as institutional providers under the TRICARE Program and modify TRICARE reimbursement of ESRD facilities.

ESRD Background and Coverage

ESRD is the fifth and final stage of Chronic Kidney Disease and necessitates long-term dialysis or a kidney transplant; without treatment, death is imminent. There are three treatment options for ESRD, including two types of dialysis. First, patients may receive a kidney transplant; however, there are approximately 100,000 individuals on the national kidney transplant list at any given point in time, but only 20,000 kidneys available each year in the United States. Consequently, most ESRD patients receive dialysis until they can receive a kidney transplant from a suitable donor. A patient may receive hemodialysis, in which the patient's blood is filtered externally before being returned to the body. Most patients (86%) begin ESRD treatment receiving this type of dialysis, which can be performed at home or in an inpatient or outpatient medical facility. Alternatively, a patient may receive peritoneal dialysis, in which fluid is injected into the patient's abdomen, blood is filtered, and waste is filtered out through a semi-permanent tube. Although this type of dialysis can be performed in a patient's home, fewer than 11% of patients begin ESRD receiving this type of dialysis. The remaining 3% of patients beginning ESRD treatment receive a preemptive kidney transplant.

In 1972, Congress passed an amendment to the Social Security Act (Pub. L. 92–603), which added ESRD to the list of qualifying conditions for which a person is entitled to enroll in Medicare. ESRD patients under the age of 65 must undergo a waiting period before being able to enroll in Medicare. Currently, TRICARE beneficiaries are eligible for Medicare coverage on the basis of an ESRD diagnosis on the first day of the fourth month of dialysis treatment, after which the beneficiary, if enrolled in Medicare, becomes dual eligible (*i.e.,* both a beneficiary of TRICARE and Medicare). Therefore, for those beneficiaries enrolled in Medicare, TRICARE is first payer during the first three months of dialysis treatment for beneficiaries under age 65 and is second payer starting with the fourth month of treatment. Approximately 500 to 600 TRICARE beneficiaries who are not already enrolled to Medicare receive dialysis each year. Most claims for dialysis received by TRICARE (approximately 90%) are for individuals with both TRICARE and Medicare eligibility.

Freestanding ESRD Facilities

The term ''freestanding ESRD facilities'' refers to non-hospital, freestanding providers that render services and supplies related to ESRD, including outpatient dialysis treatments, home dialysis training and equipment, drugs and biologicals, laboratory tests, and nursing services. Freestanding ESRD facilities may also provide dialysis services for acute kidney injury (AKI), and will be reimbursed for AKI services under the provisions established in this IFR. ESRD facilities may also be known as Dialysis Facilities and Dialysis Centers, and they include both freestanding and hospital-based providers. Hospital-based ESRD facilities are already reimbursed for their institutional charges by TRICARE, generally under the Outpatient Prospective Payment System (OPPS) or other rules that apply to special hospitals, such as Critical Access Hospitals; this IFR concerns freestanding ESRD facilities only. TRICARE utilizes Medicare's classification for determining if a facility is hospital-based (42 CFR 413.174). If Medicare considers a dialysis treatment facility to be hospital-based or part of a hospital outpatient department, TRICARE accepts that determination without exception. No changes will be made to hospital-based ESRD facilities as a result of this IFR. They will continue to be reimbursed on the basis of OPPS, or in the case of Sole Community Hospitals, Critical Access Hospitals, or other special providers (*e.g.,* Cancer and Children's hospitals), on the basis of existing reimbursement methodologies.

Currently, freestanding ESRD facilities are considered non-institutional CSPs under the TRICARE Program and are not considered institutional providers, as described in 32 CFR 199.6(b). As a result, these providers can only be reimbursed for professional services and for covered supplies and pharmaceuticals on a FFS basis. CSPs may not be reimbursed for institutional services outlined in 32 CFR 199.4(b), such as the use of special treatment rooms, general staff nursing services, and room and board. In order to modify TRICARE reimbursement of ESRD facilities to better reflect Medicare's ESRD PPS (*e.g.,* to include payment for institutional services), freestanding ESRD facilities must first be classified as authorized institutional providers under the TRICARE Program in § 199.6.

Title 42 CFR part 494 provides Medicare's Conditions for Coverage for both hospital-based and freestanding ESRD Facilities. As ESRD is a Medicare-qualifying condition, we find it appropriate to adopt Medicare approval of freestanding ESRD facilities, including all Medicare conditions for coverage required for Medicare approval of freestanding ESRD facilities, in order to be an authorized TRICARE ESRD facility and receive payment under the TRICARE program. Those ESRD facilities that qualify to be an authorized TRICARE ESRD institutional provider on the effective date of this IFR may apply for TRICARE authorized provider status and be reimbursed under the new TRICARE reimbursement methodology for ESRD facilities for covered services furnished to an eligible TRICARE beneficiary on or after the IFR effective date. No new TRICARE CSP participation agreements will be accepted for coverage of ESRD services on or after the effective date of this IFR, and all current TRICARE CSP participation agreements will be terminated from freestanding ESRD facilities on the effective date of this IFR. Only ESRD services furnished by hospital-based ESRD facilities and TRICARE authorized freestanding ESRD facilities will qualify as TRICARE

covered services. We encourage comments on whether TRICARE should consider any additional criteria for freestanding ESRD facilities to be considered TRICARE-authorized institutional providers.

Reimbursement

In 2011, CMS established the ESRD PPS, which is the methodology used to reimburse ESRD facilities. The ESRD PPS pays facilities a case-mix adjusted rate for dialysis services, per dialysis treatment, including drugs, laboratory tests, and supplies. The specific rate varies by patient characteristics (*e.g.,* age, body surface area, body mass index, co-morbidities, date of onset of dialysis) and facility characteristics (*e.g.,* area wage-index, treatment volume, and rural location). The base rate and methodology are updated annually in the Medicare ESRD PPS Final Rule, published in the **Federal Register**; in Calendar Year (CY) 2021, the base rate was $253.13 and in CY22, the base rate was $257.90 (86 FR 61874).

Additionally, facilities may receive separately-paid outlier payments if a patient's treatment costs exceed a specified threshold for certain items. Facilities may also be paid separately for certain drugs and supplies, using add-on payments known as Transitional Drug Add-on Payment Adjustment and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies. Once approved for a specific drug or supply, the add-on payment is applied for two years, after which the reimbursement for these products is bundled into the base payment amount. CMS has also established a Quality Incentive Program (QIP) for reimbursement of ESRD facilities.

As discussed above, DHA reimburses dialysis services on a FFS basis for the covered professional services and supplies only, as freestanding ESRD facilities are not classified as institutional providers in 32 CFR 199.6. Currently, most freestanding ESRD facilities are only eligible to be considered CSPs, as defined in 32 CFR 199.6(f). The CSP class of providers consists of freestanding corporations and providers that render principally professional, ambulatory, or in-home care and technical diagnostic procedures. The intent behind CSPs is not to create additional benefits that ordinarily would not be covered under TRICARE if provided by a more traditional health care delivery system, but rather to allow cost-sharing for services which would otherwise be allowed except for an authorized individual professional provider's affiliation with a freestanding corporate entity, such as a medical doctor or physical therapist employed directly with a freestanding corporate entity or foundation. This limits reimbursement for freestanding ESRD facilities qualifying as CSPs to only professional services, along with supplies and drugs, and excludes reimbursement of facility charges, such as general nursing services and reimbursement for the use of treatment rooms.

This rule will establish a TRICARE reimbursement methodology for freestanding ESRD facilities to better reflect the Medicare reimbursement rate under the Medicare ESRD PPS by recognizing freestanding ESRD facilities as authorized institutional providers and permitting reimbursement of facility charges. In 2021, freestanding ESRD providers were paid, via the CHAMPUS Maximum Allowable Charge Method (CMAC), approximately $119 per session, on average, for professional services, plus an additional average of $125 for supplementary drugs, tests, and supplies, leading to an average per-session reimbursement of approximately $244. While this rate was roughly comparable to the Medicare base rate, it does not account for other adjustments and modifications made by Medicare to the base rate as part of the Medicare ESRD PPS.

Medicare adjusts the base rate for patient-level characteristics, including age, body mass index, specific conditions, and date of onset, as well as facility-level characteristics such as wage-index, low-volume factors, rural locations, and outlier payments. Medicare also provides a separate payment for certain exceptional drugs or equipment and supply items during a transitional status. Finally, Medicare continues to refine the system through the QIP.

Our analysis has shown that the two most important factors in Medicare's adjustment of the base rate that would apply to TRICARE's population are age and date of onset. The age adjustment factor is approximately 7% for patients ages 44–69. We found that over 70% of TRICARE ESRD patients where TRICARE is the primary payer are between the ages of 44–69, and thus we think that a 7% adjustment would be practicable. A more important factor is the 32.7% adjustment used by Medicare for patients in the first four months since the onset of dialysis.

In lieu of the current method of reimbursement utilizing the CMAC for the professional charges plus additional allowed amounts for laboratory, pharmaceuticals, and supplies (with no reimbursement for facility charges), under the provisions of this rule, TRICARE will reimburse a single, flat, per-session fee which will include all charges for the facility use, general nursing services, laboratory services related to ESRD care, pharmaceuticals (excepting those allowed for separate payment by Medicare), and supplies. The TRICARE ESRD rate will have a higher reimbursement for the first 120 days of dialysis, and a different, lower rate for days 121 and later where TRICARE is the primary payer. This reflects Medicare's adjustment of 32.7% for the first four months of ESRD treatment. We also propose to add a 7% adjustment to each rate (*i.e.* both for 0–120 days and 121 days and later) to account for the fact that approximately 70% of the beneficiaries receiving ESRD care for which TRICARE is the primary payer are between ages 44 and 69. Additionally, to account for training services and supplies, dialysis training sessions will receive a home dialysis training add-on payment for day treatment days 121 and after. The training add-on payment will not apply to treatment days 1–120, as the onset adjustment factor of 32.7% is applied to the per-session rate for treatment days 1–120. The rates below use CY 2021 rates as an example.

	CY 2021 TRICARE FFS methodology average	CY 2021 Medicare base rate	Proposed TRICARE 2021 rate— first 120 days	Proposed TRICARE 2021 rate— 121 days and later
Per Session Reimbursement, CY 21.	$244	$253.13	$359.42	$270.85.
Reimbursement Components	$119 for the Professional Charge plus $125 for Lab, Drugs, and Supplies.	Medicare Published Base Rate	Medicare Base Rate multiplied by: 7% Age Adjustment; 32.7% Onset Adjustment.	Medicare Base Rate multiplied by: 7% Age Adjustment.

As stated above, this fee will incorporate all ESRD-related laboratory services, pharmaceuticals, and supplies required in the course of the dialysis treatment. The flat rates above also apply to renal dialysis services furnished to TRICARE beneficiaries for home dialysis services, which include: home dialysis support services identified at 42 CFR 494.100; the purchase and delivery of all necessary home dialysis supplies; and dialysis training for days 1–120. The authorized TRICARE ESRD institutional provider will receive the same reimbursement rate for home dialysis services as it would receive for in-facility dialysis services. All renal dialysis items and services furnished in the ESRD facility or in a patient's home are included in the rates above and must be furnished by the ESRD facility, either directly or under an arrangement. Only the following services will be allowed separate reimbursement:

- Evaluation and management services rendered by authorized individual professional providers (*e.g.,* a nephrologist evaluating the patient). These services will continue to be reimbursed via the CMAC system.
- Drugs, supplies, and devices listed by Medicare as eligible for Transitional Drug Add-on Payment Adjustment and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies. These services may be reimbursed via the CMAC and/or Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) reimbursement system (*e.g.,* reimbursement for drugs may be made using existing policy on the reimbursement of medical claims that include drugs), and in cases where no CMAC, DMEPOS, or other rate exists, TRICARE will reimburse on the basis of billed charges, subject to the provisions of 32 CFR 199.9, administrative remedies for fraud and abuse. Information on these items can be found in the Medicare website sections outlining the ESRD PPS. [*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug* and *https://www.cms.gov/medicare/esrd-pps/esrd-pps-transitional-add-payment-adjustment-new-and-innovative-equipment-and-supplies-tpnies*].
- Services unrelated to ESRD care (*e.g.,* if a flu shot is administered at the same time as dialysis treatment). These services will continue to be reimbursed using existing reimbursement systems (*e.g.,* CMAC).

The flat rate shall be updated each year by utilizing the Medicare base rate, promulgated in their annual ESRD PPS final rule, and by adjusting it using the age adjustment factor for individuals aged 44–69 (currently 7%, however, if Medicare modifies this adjustment factor in subsequent years DHA will utilize the updated factor) and the Medicare adjustment factor for date of onset (currently 32.7%, however, if Medicare modifies this adjustment factor in subsequent years DHA will utilize the updated factor).

The flat rate also will be wage adjusted to provide adequate locality adjustments, using the wage indices published by Medicare for the ESRD PPS. This adjustment serves to more appropriately reimburse freestanding ESRD facilities based on their locality (*e.g.,* higher cost areas receive higher reimbursement than lower-cost areas). Both Medicare and TRICARE reimbursement methodologies for other provider types use a similar methodology to appropriately reimburse providers based on locality; the Medicare ESRD PPS likewise uses an area wage-index adjustment to the base rate for this purpose. TRICARE's ESRD reimbursement methodology will apply the wage adjustment factor to the same percentage of the base rate as specified by CMS in the ESRD PPS, including any future updates by CMS in the ESRD final rule. Therefore, the TRICARE ESRD reimbursement methodology will approximate the Medicare methodology in the ESRD PPS. DHA will issue policy regarding the precise reimbursement methodology for freestanding ESRD facilities in its implementing instructions, and will provide an annual listing of rates on its website at *www.health.mil/rates* within 90 days of issuance of the Medicare Final Rule containing the updated base rate.

This reimbursement approach approximates, but does not duplicate, Medicare's ESRD PPS. It is not practicable for DHA to implement Medicare's ESRD PPS because of the small number of beneficiaries for which TRICARE is the primary payer. The administrative start-up and ongoing maintenance costs of implementing such a complex system would outweigh benefits of adoption. We believe that this flat payment, one for the first 120 days, and another for 121 days and later, sufficiently retains the intent to reimburse like Medicare to the extent practicable, while also ensuring adequate reimbursement for ESRD services delivered at freestanding ESRD facilities.

We invite comments on this methodology and may make further refinements through the issuance of a Final Rule.

Copayments and Cost-Sharing

Treatment in freestanding ESRD facilities (including home dialysis services) shall be considered specialty outpatient visits for the purposes of cost-sharing and copayments under the program. Applicable copayments and cost-shares as described in 32 CFR 199.4 and 199.17(k)(2)(iii) will apply upon publication of this rule.

DRG Add-On Payment for NCTAP

This provision, 32 CFR 199.14(a)(1)(iv)(C), temporarily adopts Medicare's NCTAP for services and supplies otherwise covered under the TRICARE Program, including adopting Medicare's termination date for NCTAPs, which CMS extended for discharges that occur through the end of the FY in which the PHE terminates. TRICARE shall reimburse acute care hospitals an NCTAP amount which is the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the CARES Act, for certain cases that include the use of a drug or biological product currently authorized or approved for treating COVID–19. The NCTAP will not be included as part of the calculation of the operating outlier payments. Providers must submit claims in accordance with the TRICARE claims filing deadline requirements, which are located in the TRICARE implementing instructions (*i.e.,* the TRICARE manuals).

D. Legal Authority for This Program

This rule is issued under 10 U.S.C. 1073(a)(2) giving authority and responsibility to the Secretary of Defense to administer the TRICARE program. The statutory requirements to reimburse individual and institutional providers for like services and supplies using the same methodologies as Medicare are located in 10 U.S.C. 1079(h) and (i), respectively. The text of 10 U.S.C. chapter 55 can be found at *https://manuals.health.mil/.*

II. Regulatory History

Each of the sections being modified by this rule are revised every few years to ensure requirements continue to align with the evolving health care field.

Title 32 CFR 199.6 was last modified November 17, 2020 (85 FR 73196). This change added Doctors of Podiatric Medicine and Podiatrists as allied health professionals under the TRICARE Program, added referral and supervision requirements for physical therapists and occupational therapists, and added

speech pathologists as paramedical providers under the TRICARE Program.

Title 32 CFR 199.14 was last modified September 3, 2020 (85 FR 54924). This change added multiple provisions related to the COVID–19 pandemic (*i.e.,* adjusting DRG and long-term care facility payments), adopted Medicare New Technology Add-On Payments, and adopted Medicare Hospital Value Based Program adjustments.

III. Regulatory Analysis

A. Regulatory Planning and Review

a. Executive Orders

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Accordingly, the rule has been reviewed by the Office of Management and Budget under the requirements of these Executive Orders. This rule has been designated a ''significant regulatory action'' although determined to be not economically significant, under section 3(f) of Executive Order 12866.

b. Summary

The modifications to paragraphs 199.6(b)(4)(xxi) and 199.14(c) in this IFR will establish freestanding ESRD facilities as a category of institutional provider within the TRICARE program and will create a TRICARE reimbursement system for those facilities. These changes will make TRICARE reimbursement of freestanding ESRD facilities, as well as dialysis services and supplies provided by these facilities, more consistent with the Medicare PPS rates for ESRD facilities, in accordance with the statutory requirement to reimburse like Medicare for like services and supplies to providers of services of the same type (*i.e.,* institutional providers) except when impracticable. These changes will also allow for TRICARE payment of institutional services rendered by freestanding ESRD facilities. The modification to paragraph 199.14(c) will require the deletion of a now-defunct provision, that the Director, DHA, shall establish reimbursement for institutions other than hospitals and Skilled Nursing Facilities. Since the new ESRD reimbursement provisions will be moved to paragraph 199.14(c), and since 10 U.S.C 1079(i)(2) requires amounts to be paid to institutions to be prescribed in regulation, the existing requirement in 199.14(c) is unnecessary and will be deleted from regulation.

The modifications to paragraph 199.14(a)(1)(iv)(C) in this IFR will temporarily adopt the Medicare NCTAP for COVID–19 patients through the end of the FY in which the PHE terminates. The NCTAP provides additional reimbursement in addition to the 20 percent add-on payment under section 3710 of the CARES Act equal to the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the CARES Act, for certain cases that include the use of a drug or biological product currently authorized or approved for treating COVID–19. NCTAP claims are those that are eligible for the 20 percent add-on payment indicated by the presence of COVID diagnosis codes, plus the presence of certain procedure codes for certain COVID–19 treatments including remdesivir, or convalescent plasma.

c. Affected Population

This change impacts all TRICARE beneficiaries who require dialysis, who are receiving COVID–19 treatments eligible for NCTAPs, or who require medically necessary services during the COVID–19 pandemic. Providers who render treatments eligible for NCTAPs will be impacted by being able to receive higher, more appropriate reimbursement from TRICARE than they would have in the absence of this rule. Providers may also experience decreased patient volume burden if their patients with ESRD are able to be treated in a freestanding ESRD facility instead. Freestanding ESRD facilities will be impacted by receiving higher reimbursement for care provided to TRICARE beneficiaries who have not enrolled in Medicare. TRICARE's health care contractors will be impacted by being required to implement the provisions of this regulatory change. State, local, and tribal governments will not be impacted.

d. Costs

The cost estimates related to the changes discussed in this IFR include incremental health care cost increases (also known as transfer costs) as well as administrative costs to the government. Only the ESRD provisions will result in recurring incremental health care costs, while the NCTAP provision will result in cost increases from the effective date of the IFR though the FY in which the PHE terminates. The cost estimate assumes that the PHE continues into, but not beyond, FY 2023; however, the COVID–19 pandemic contains substantial uncertainty including the possibility of additional COVID–19 variants resistant to current vaccines and treatments, as well as the actual date the PHE terminates. As such, we find it appropriate to make these regulatory changes despite the potential short effective period, as the end of the pandemic is by no means a certainty.

Based on these factors, as well as the assumptions for each provision detailed below, we estimate that the total cost estimate for this IFR through FY 2023 will be approximately $8.08M. This estimate includes approximately $0.75M in administrative costs and $7.33M in direct health care costs. The NCTAP provision is expected to have costs through FY 2023, while the permanent ESRD provisions are expected to result in $5.23M in incremental annual costs, with a 4.5% increase each subsequent year due to inflation and an increase in cases.

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

Provision	FY23 costs
ESRD	$5.23M
DRG Add-on for NCTAP	2.1
Administrative costs	0.75
Estimated Total Cost Impact	8.08M

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

• *Freestanding ESRD Facilities.* We assumed that the number of TRICARE beneficiaries requiring ESRD services, the proportion of beneficiaries receiving acute versus chronic dialysis, and the number of each type of ESRD service (*e.g.,* dialysis, lab services, medical supplies, pharmaceuticals) for which TRICARE was the primary payer will remain constant. This estimate assumes paying freestanding ESRDs a facility charge for the first 120 days of dialysis equal to the base payment rate under the Medicare ESRD PPS multiplied by the 7 percent factor (for age) and the 32.7 percent factor (for the first 120 days of dialysis). This base rate would be further adjusted for locality using a wage index adjustment factor, using the same or similar adjustments as

Medicare, as appropriate. For ESRD services past 120 days of dialysis, the cost estimate assumed only the seven percent adjustment factor for age and the wage index adjustment factor locality would be applied. Any services or supplies not included in Medicare's ESRD PPS bundle would continue to be reimbursed separately by TRICARE using the applicable existing reimbursement methodology. The cost estimate of $5.23M annually was calculated by multiplying the base amount plus applicable adjustments by the number of ESRD claims for which TRICARE would be the primary payer, although this amount will increase by a small 4.5% adjustment factor annually. Additionally, we expect this provision to result in approximately $340,000 in one-time administrative costs.

• *DRG Add-on for NCTAP.* This estimate assumes an effective date for this provision of October 1, 2022 and that the PHE will end during FY23. In creating this estimate, we first analyzed TRICARE inpatient claims at private sector hospitals and identified that almost half of inpatient admissions also had a procedure code treatment with at least one of the selected therapies eligible for NCTAP add-on payments. We identified from TRICARE actual data that there were 6,600 total TRICARE COVID–19 admissions during the November 2020–June 2021 period; 3,000 of these admissions included a treatment eligible for an NCTAP and 1,400 of those treatments had a cost that exceeded the DRG payment. Therefore, we assumed 21 percent (*i.e.,* 1,400 divided by 6,000) of total TRICARE COVID–19 treatments would qualify for an NCTAP. Towards the end of the PHE, we expect fewer admissions due to decreasing hospitalization rates, and thus we assumed approximately 100 admissions per month in FY23. To estimate direct health care costs, we assumed that 21 percent of the projected TRICARE COVID–19 admissions would be paid the NCTAP of 65 percent of the amount by which the costs of the case exceed the standard DRG payment. We calculated an average NCTAP of $8,450 per case by identifying the TRICARE COVID–19 private sector cases in which the COVID–19 treatment exceeded the DRG payment, calculating the average excess cost per case, and multiplying this average excess cost by 65 percent. We multiplied the average expected NCTAP of $8,450 by the expected number of monthly TRICARE private sector hospitalizations projected to be affected by this provision and estimated $2.1M in incremental direct health care costs in FY23. We also estimated administrative start-up costs of $410,000 for the Managed Care Support Contractors to maintain a list of approved NCTAPs, identify which claims are eligible for a NCTAP, and to calculate the estimated NCTAP amount for each claim.

e. Benefits

Freestanding ESRD facilities will be positively impacted by increased reimbursement and may improve both the access to and quality of care patients receive, which will in turn benefit TRICARE beneficiaries with ESRD, a chronic, life-threatening condition. Providers rendering treatments to patients with COVID–19 will benefit by receiving higher, more adequate reimbursement for services and supplies eligible for an NCTAP. Both providers and patients requiring emergency or inpatient treatment will benefit if TRICARE beneficiaries with ESRD are treated in a freestanding ESRD facility rather than in an emergency department or inpatient hospital during any future COVID–19 surges.

f. Alternatives

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

The second alternative, related to the provisions regarding freestanding ESRD facilities, was to adopt Medicare's reimbursement system (the ESRD PPS) in total. The advantages of this option were:

• It is completely consistent with the statutory provision to pay institutional providers using the same methodology as Medicare;

• It would provide the nuanced payment differences made by Medicare on the basis of age, comorbidities, body measurements, and facility-specific adjustments for low-volume facilities and rural facilities;

• It would accommodate outlier payments and cases; and

• It contains provisions for a QIP.

However, this option was not pursued because of the very low volume of TRICARE beneficiaries who receive dialysis services from freestanding ESRDs and who are not enrolled to Medicare. Most dialysis services that are paid by TRICARE are for individuals who are both Medicare and TRICARE eligible (approximately 90% of claims for dialysis services in FY 2019 were for patients where Medicare was the primary payer). In these cases, where Medicare pays as primary, TRICARE generally provides reimbursement for the remaining patient liability, which was approximately $44 per treatment in FY 2019. Thus, for 90% of dialysis claims received by TRICARE, TRICARE is already following Medicare reimbursement methods, as the remaining patient liability is less than what would have otherwise been paid had TRICARE been the primary payer, in accordance with TRICARE regulations regarding other health insurance and dual eligibility. The cost of implementing the full ESRD PPS system is estimated to be at least $600,000 in start-up costs, plus ongoing administrative costs, to ensure all adjustments were made for each claim, plus additional special pricing software or algorithms. Additional administrative funds may be required to implement the QIP and other programs, as implemented by Medicare now or in the future. Further, implementation of the ESRD PPS would be time-consuming, taking up to a year to accomplish. In contrast, we estimate that the option provided in this IFR can be implemented relatively quickly, and for approximately $340,000 in start-up costs with lower ongoing administrative costs. Further, the flat rate will provide the ESRD facilities with predictability with regard to TRICARE payments and will reduce uncertainty and specialized coding or case-mix documentation requirements that may be required by the ESRD PPS, reducing the administrative burden on the provider. To summarize, adopting the ESRD PPS was considered, but was deemed impracticable and overly burdensome to both the Government and providers.

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

The ASD(HA) certified that this IFR is not subject to the flexibility analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. The great majority of hospitals, freestanding ESRDs, pharmacies, and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any one year). Individuals and States are not included in the definition of a small entity.

All of the provisions of this IFR are likely to have an economic impact on health care providers and suppliers. As its measure of significant economic impact on a substantial number of small entities, HHS uses an adverse change in revenue of more than 3 to 5 percent. While TRICARE is not required to follow this guidance in the issuance of our rules, we provide this metric for context, given that these temporary changes align with similar changes made by Medicare. Given that all provisions within this rule are likely to increase reimbursement to providers and suppliers, we find that these provisions would not have an adverse impact on revenue and, therefore, would not have a significant impact on these providers meeting the definition of small business.

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

C. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

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

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

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

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

F. Executive Order 13132, ''Federalism''

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

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

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on one or more Indian tribes, preempts tribal law, or effects the distribution of power and responsibilities between the Federal Government and Indian tribes. This rule will not have a substantial effect on Indian tribal governments.

List of Subjects in 32 CFR Part 199

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

Accordingly, 32 CFR part 199 is amended as follows:

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

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

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

■ 2. Amend § 199.6 by adding paragraph (b)(4)(xxi) and revising paragraph (f)(1)(i) to read as follows:

§ 199.6 TRICARE-authorized providers.

* * * * *

(b) * * *

(4) * * *

(xxi) *Freestanding End Stage Renal Disease (ESRD) facilities.* Freestanding ESRD facilities must be Medicare certified and meet all Medicare conditions for coverage as provided in 42 CFR part 494, and be classified as freestanding ESRD facilities by Medicare, in order to be approved as TRICARE-authorized institutional providers and receive payment under the TRICARE program. State licensing are not required in cases of a freestanding ESRD facility located in a State that does not license such facilities. Freestanding ESRD facilities are not hospital-affiliated nor hospital-based and are reimbursed based on the payment methodology established in § 199.14(c). Freestanding ESRD facilities render outpatient hemodialysis or peritoneal dialysis services in the ESRD facility or in a patient's home for the treatment of ESRD and acute kidney injury (AKI).

* * * * *

(f) * * *

(1) * * *

(i) This corporate services provider class is established to accommodate individuals who would meet the criteria for status as a CHAMPUS authorized individual professional provider as established by paragraph (c) of this section but for the fact that they are employed directly or contractually by a corporation or foundation that provides principally professional services which are within the scope of the CHAMPUS benefit. With authorization of freestanding end stage renal disease (ESRD) facilities as TRICARE institutional providers under paragraph (b)(4)(xxi) of this section, corporate service provider status will not be authorized for the provision of ESRD services.

* * * * *

■ 3. Amend § 199.14 by adding paragraph (a)(1)(iv)(C) and revising paragraph (c) to read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *

(1) * * *

(iv) * * *

(C) *Additional payment for new COVID–19 Treatments.* TRICARE will adopt the Medicare New COVID–19 Treatments Add-On Payments (NCTAP) adjustment to DRGs. New COVID–19 treatments shall be reimbursed the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment for an individual treated using new COVID–19 treatments discharged during the Secretary of Health and Human Services' declared public health emergency (PHE) through the end of the FY in which the PHE terminates.

* * * * *

(c) *Reimbursement of Freestanding End Stage Renal Disease (ESRD) facilities.* (1) This paragraph (c)(1) establishes payment methods for dialysis provided by TRICARE authorized freestanding ESRD facilities. TRICARE shall reimburse a single, flat, per-session fee to TRICARE authorized freestanding ESRD facilities rendering hemodialysis or peritoneal dialysis for treatment of ESRD or AKI. The flat, per-session fee will apply to renal dialysis services furnished in the ESRD facility or in a patient's home. All renal dialysis items and services furnished in the ESRD facility or in a patient's home are included in the flat per-session rate, except for those items and services listed in paragraph (c)(1)(ii) of this section.

(i) Services included in the flat per-session rate must be furnished by an authorized TRICARE ESRD institutional provider:

(A) Institutional charges (*e.g.,* charges for facility use, use or treatment rooms, and general nursing services);

(B) Routine laboratory services related to the dialysis session;

(C) Pharmaceuticals and supplies related to the dialysis;

(D) Home dialysis support services identified at 42 CFR 494.100;

(E) Purchase and delivery of all necessary home dialysis supplies; and

(F) Dialysis training for days 1–120.

(ii) Services which may be billed separately:

(A) Evaluation and management services provided by authorized individual professional providers. These services will continue to be reimbursed using existing reimbursement systems (*e.g.,* CMAC).

(B) Drugs, supplies, and devices listed by Medicare as eligible for Transitional Drug Add-on Payment Adjustment and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies under the Medicare ESRD PPS. These services will continue to be reimbursed using existing reimbursement systems (*e.g.,* CMAC).

(C) Professional services, supplies, and pharmaceuticals unrelated to dialysis care (*e.g.,* if a flu shot is administered at the same time as dialysis treatment). These services will continue to be reimbursed using existing reimbursement systems (*e.g.,* CMAC).

(iii) Establishment of the flat rate:

(A) *Per session rate for treatment days 1–120.* The flat, per-session rate shall be equal to the current Medicare base rate, multiplied by the current Medicare adjustment factor applied to individuals aged 44–69 (7% for CY 22), and further multiplied by the current Medicare adjustment factor for the date of onset (32.7% for CY 2022). The Medicare factors utilized in subsequent years will be based on modifications made under 42 CFR part 413, subpart H, Medicare ESRD PPS.

(B) *Per session rate for treatment day 121 and beyond.* The flat, per-session rate shall be equal to the Medicare base rate, multiplied by the Medicare adjustment factor applied to individuals aged 44–69. The Medicare factors utilized in subsequent years will be based on modifications made under 42 CFR part 413, subpart H, Medicare ESRD PPS.

(C) *Wage adjustment.* The per-session rates in paragraphs (c)(1)(iii)(A) and (B) of this section shall be wage adjusted using the wage adjustment factors and labor-related shares published in the most recent Medicare ESRD Final Rule at the time the annual per-session rates are posted.

(D) *Annual updates.* The per session rates will be updated within 90 days of publication of new Medicare base rates, and published to the TRICARE website at *www.health.mil.*

(E) *Dialysis training.* To account for training services and supplies, dialysis training sessions will receive a home dialysis training add-on payment for day treatment days 121 and after. The training add-on payment will not apply to treatment days 1–120, as the onset adjustment factor of 32.7% is applied to the per-session rate for treatment days 1–120.

(2) The reimbursement methods established in paragraph (c)(1) of this section applies to freestanding ESRD facilities meeting the requirements established for TRICARE authorized freestanding ESRD facilities in § 199.6. For purposes of cost-sharing and copayments, treatment provided by freestanding ESRD facilities are considered outpatient specialty visits. The applicable copayments and cost-shares described in §§ 199.4 and 199.17(k)(2)(iii) shall apply. Hospital-based ESRD facilities are not subject to the provisions of this paragraph, and will continue to be reimbursed utilizing other applicable reimbursement systems (*e.g.,* the Outpatient Prospective Payment System).

* * * * *

Dated: January 6, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0002]

RIN 1625–AA00

Safety Zone; Chinese Harbor; Santa Cruz Island, California

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The U.S. Coast Guard is establishing a temporary safety zone for the navigable waters in Chinese Harbor of Santa Cruz Island, California. This safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by ongoing oil recovery and salvage operations relating to the grounding of a 60-foot fishing vessel in Chinese Harbor. Entry of persons or vessels into this safety zone is prohibited unless specifically authorized by the Captain of the Port Los Angeles—Long Beach (COTP), or their designated representative.

DATES: This rule is effective without actual notice from January 12, 2023 until January 23, 2023. For the purposes of enforcement, actual notice will be used from January 5, 2023, until January 12, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2023–0002 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LCDR Maria Wiener, Waterways Management, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 357–1603, email *D11-SMB-SectorLALB-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
LLNR Light List Number
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) because it is impracticable. This is an emergency response to a vessel grounding and immediate action is needed to respond to potential safety hazards associated with the emergency oil recovery operations. It is impracticable to publish an NPRM because we must establish this safety zone by January 05, 2023.