**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**32 CFR Part 199**

**[Docket ID: DOD–2020–HA–0050]**

**RIN 0720–AB83**

## TRICARE Coverage of Clinical Trials and Termination of Expanded Access Treatments

**AGENCY:** Defense Health Agency (DHA), Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** The Assistant Secretary of Defense for Health Affairs (ASD(HA)) issues this final rule regarding circumstances under which services and supplies related to emerging treatments may be covered under the TRICARE program. This rule finalizes provisions published in two interim final rules (IFRs) with request for comment, which temporarily added coverage for the treatment use of investigational drugs under U.S. Food and Drug Administration (FDA)-authorized expanded access (EA) programs when for the treatment of coronavirus disease 2019 (COVID–19) and permitted coverage of National Institute of Allergy and Infectious Disease (NIAID)-sponsored clinical trials for the treatment or prevention of COVID–19. This final rule discusses the DoD's decision not to make permanent the coverage of treatment use of investigational drugs under FDA EA programs while updating language for care associated with their administration and broadens the COVID–19 clinical trial benefit to include coverage of clinical trials sponsored or approved by any National Institutes of Health (NIH) Center or Institute to treat or prevent infectious diseases associated with a pandemic or epidemic. Lastly, the final rule expands TRICARE's clinical trial benefit by covering services and supplies provided in conjunction with Phase I, II, III, and IV clinical trials that are NIH-sponsored or approved and that involve a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition is severely debilitating, life-threatening, or a rare disease.

**DATES:** This rule is effective on August 27, 2025.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Stankovic, Medical Benefits and Reimbursement Section, 303–676–3742, *Jennifer.L.Stankovic.civ@health.mil.*

**SUPPLEMENTARY INFORMATION:**

### Discussion of Comments and Changes

The IFR titled ''TRICARE Coverage of Certain Medical Benefits in Response to the COVID–19 Pandemic'' published in the **Federal Register** on September 3, 2020 (85 FR 54914–54924), and public comments were allowed for 60 days. A total of four comments were submitted. Two comments were generally supportive of the provisions implemented in that IFR; the DoD is grateful to the public for their support. Comments specific to provisions of that IFR not covered in this final rule were discussed in full in a final rule titled ''TRICARE Coverage and Reimbursement of Certain Services Resulting From Temporary Program Changes in Response to the COVID–19 Pandemic'' that published on June 1, 2022 (87 FR 33001–33015). In the IFR of September 3, 2020, the DoD specifically asked for comments on potentially making coverage of treatment use of investigational drugs under FDA EA programs for the treatment of COVID–19 permanent and on permanently covering the drugs for all diseases. No comments were received specific to the coverage of treatment use of investigational drugs on a permanent basis, either for the treatment of COVID–19 or for the treatment of other diseases. This final rule clarifies the DoD's decision not to add permanent coverage of investigational drugs authorized for treatment use under FDA EA programs when prescribed for the treatment of COVID–19 or for other diseases. This decision was based primarily on analysis discussed later in this rule rather than the lack of comments received on this provision. The COVID–19 national emergency terminated on April 10, 2023. As the DoD is not making the provision authorizing investigational drugs for COVID–19 under FDA EA programs permanent, this final rule will remove the temporary provision from Title 32, Code of Federal Regulation (CFR), Part 199. This final rule also modifies language in the note to § 199.4(g)(15)(i)(A) by replacing the terms ''Treatment Investigational New Drugs (INDs)'' and ''Treatment INDs'' with ''investigational drugs authorized for treatment use under FDA expanded access programs'' to better reflect updated practices and terminology associated with FDA EA programs.

The IFR titled ''TRICARE Coverage of National Institute of Allergy and Infectious Disease Coronavirus Disease 2019 Clinical Trials,'' which discussed temporary coverage of NIAID-sponsored clinical trials for the treatment of COVID–19, published in the **Federal Register** on October 30, 2020 (85 FR 68753–68758). Comments were accepted for 30 days, and the DoD received four comments. The DoD thanks all commenters for their submissions. In the COVID–19 Clinical Trials IFR, the DoD specifically solicited comments on the potential expansion of TRICARE's clinical trial benefit beyond cancer clinical trials and NIAID-sponsored COVID–19 clinical trials. Two comments were generally supportive of expanding the clinical trial benefit, while the other two comments discussed the TRICARE benefit in general. The DoD received one comment discussing the importance of clinical trials in assisting with the development of products to prevent COVID–19 cases, treat COVID–19 more efficaciously, and treat severe COVID–19 complications. This comment also recommended covering expenses related to clinical trials for other life-threatening conditions that impact a large number of beneficiaries, such as cardiovascular diseases, to improve health outcomes for beneficiaries, and to support the advancement of effective clinical treatments. The DoD received one comment recommending that coverage of COVID–19 clinical trials be made permanent.

Due in part to these comments and the DoD's comprehensive review of TRICARE's clinical trials and other investigational treatment benefits, which is discussed further in-depth within the Discussion and Regulatory Impact Analysis sections of this final rule preamble, the Department is making COVID–19 clinical trial provisions permanent. As the COVID–19 national emergency terminated on April 10, 2023, before the publication of this final rule, TRICARE will only cover routine services and supplies associated with NIAID-sponsored COVID–19 clinical trials for beneficiaries who enroll in eligible clinical trials after the effective date of this rule or who previously enrolled in an eligible clinical trial before April 11, 2023. Due to low enrollment in this benefit and the fact that beneficiaries who enroll in eligible clinical trials before the termination of the national emergency will still have routine care associated with the clinical trial covered after the termination of the national emergency, the Department expects this temporary

gap in coverage to impact few, if any, beneficiaries.

The Department is also expanding the provisions to include coverage of services and supplies provided in conjunction with clinical trials sponsored or approved by any NIH Center or Institute for the treatment or prevention of infectious diseases that cause a pandemic or epidemic and result in a Government-recognized health emergency, rather than continuing to only cover services and supplies provided in conjunction with NIAID-sponsored clinical trials for treatment or prevention of COVID–19. The DoD is promulgating this change to prepare for future health emergencies caused by infectious diseases beyond the COVID–19 pandemic, as coverage for clinical trials investigating a novel infectious disease is critical to both advancing initial research into treatments and preventive measures and fostering beneficiary access to emerging treatments. The Department is also expanding this benefit to include all NIH Centers and Institutes except for the NIH Clinical Center because NIH Centers and Institutes other than NIAID have begun conducting research on COVID–19, particularly on how the disease affects specific organ systems. Likewise, the DoD expects other NIH Centers and Institutes to conduct research on previous, current, or future pandemics and epidemics that result from infectious pathogens and cause the declaration of a national emergency or public health emergency (PHE). This change also adds authorization of NIH-approved clinical trials where NIH serves as a collaborator, rather than only NIH-sponsored clinical trials, in order to further expand access to clinical trials for TRICARE beneficiaries. This expansion of TRICARE's clinical trial benefit therefore includes coverage of NIH-sponsored or approved clinical trials for the treatment or prevention of infectious diseases that cause a pandemic or epidemic and result in a Government-recognized health emergency, including COVID–19 clinical trials, rather than just NIAID-sponsored COVID–19 clinical trials. If the Government-recognized health emergency was declared before the effective date of this rule, only services and supplies provided in conjunction with eligible clinical trials after this rule's effective date may be covered.

Lastly, the Department is expanding and modernizing the TRICARE clinical trial benefit to cover services and supplies provided in conjunction with NIH-sponsored or approved Phase I–IV clinical trials that involve a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition or uncontrolled symptom of the condition under study in the clinical trial is severely debilitating, life-threatening, or a rare disease. This includes expanding coverage of cancer clinical trials to National Cancer Institute (NCI)-sponsored or approved Phase I–IV clinical trials, rather than only NCI-sponsored Phase I–III clinical trials, as cancer is itself a life-threatening condition. This expansion of TRICARE's clinical trial benefit conforms to statutory authority and is supported by the DoD's review into the clinical trials reimbursement landscape and the comments the DoD received in response to the COVID–19 Clinical Trials IFR.

## I. Background

### *A. Statement of Need for This Rule*

In 2020, the DoD published three IFRs with request for comments to respond to the COVID–19 pandemic, which included two provisions addressed in this final rule: temporary coverage of investigational drugs authorized for treatment use under FDA EA programs and temporary coverage of services and supplies provided in conjunction with NIAID-sponsored clinical trials for the treatment or prevention of COVID–19; both provisions were originally effective for the duration of the President's declared national emergency. All other provisions of those IFRs, including the first COVID–19 IFR published by the DoD on May 12, 2020 (85 FR 27921–27927), titled ''TRICARE Coverage and Payment for Certain Services in Response to the COVID–19 Pandemic,'' were finalized in a final rule, titled ''TRICARE Coverage and Reimbursement of Certain Services Resulting From Temporary Program Changes in Response to the COVID–19 Pandemic,'' published on June 1, 2022 (87 FR 33001–33015). The DoD published a fourth IFR titled ''Expanding TRICARE Access to Care in Response to the COVID–19 Pandemic'' on January 12, 2023 (88 FR 1992–2002); its provisions have not yet been finalized in a final rule.

In addition to rulemaking, before the COVID–19 clinical trial provisions could be published, Title 10, United States Code (U.S.C.), Section 1079(a)(12) also required the DoD to first enter into an inter-agency agreement with the Secretary of the Department of Health and Human Services (HHS). Instead of entering into an agreement with NIAID only, the Department foresaw the possibility of expanding the TRICARE clinical trial benefit as authorized under 10 U.S.C. 1079(a)(12) to cover studies sponsored or approved by other NIH Centers and Institutes. The DoD therefore entered into an agreement with NIH to cover certain routine costs associated with clinical trials; this inter-agency agreement is not limited to NIAID or clinical trials related to COVID–19, although the IFR published by the DoD on October 30, 2020 (85 FR 68753–68758), titled ''TRICARE Coverage of National Institute of Allergy and Infectious Disease Coronavirus Disease 2019 Clinical Trials,'' only authorized coverage of services and supplies provided in conjunction with certain NIAID-sponsored clinical trials for the treatment or prevention of COVID–19. The inter-agency agreement includes clinical trials sponsored or approved by NIH, is effective from September 19, 2020, through September 18, 2029, and provides for both parties to review the agreement every three years.

This final rule promulgates three major changes to the provisions enacted in the IFRs in response to public comments, the COVID–19 pandemic, and the DoD's comprehensive review of the clinical trials reimbursement landscape:

#### Consideration of Permanent TRICARE Coverage of Investigational Drugs Authorized for Treatment Use Under FDA EA Programs

First, this final rule considered permanent TRICARE coverage of investigational drugs authorized for treatment use under FDA EA programs for the treatment of COVID–19. This temporary coverage was authorized in the IFR published September 3, 2020, but that authorization expired when the President's national emergency for COVID–19 ended April 10, 2023. In the IFR, the ASD(HA) stated that the DoD would consider if any permanent coverage was appropriate and publish a final rule detailing the Department's analysis and decision. While the DoD recognizes the value of access to emerging therapies, as demonstrated by its coverage of investigational drugs during the early part of the COVID–19 pandemic, there is insufficient statutory authority to permit permanent coverage. This final rule discusses the DoD's decision and adds clarifying language regarding coverage of care associated with such drugs for any disease.

The IFR authorizing temporary coverage of these drugs permitted that temporary coverage in response to the COVID–19 pandemic and stated that the DoD would consider permanent coverage after thoroughly examining the

FDA-authorized EA program and determining what coverage, if any, was appropriate given TRICARE's statutory requirement to only cover medically necessary care under 10 U.S.C. 1079(a)(12).

To determine what coverage was appropriate, the DoD examined its own regulatory history for coverage of FDA-approved drugs, as well as changes to FDA EA programs since the DoD's regulatory provisions were enacted. The DoD, under the Civilian Health and Medical Programs of the Uniformed Services (CHAMPUS) Program (now TRICARE), first established an ''absolute requirement for approval by the [FDA] of all prescription drugs and medicines'' as a criterion for coverage on November 26, 1991 (56 FR 59870). The 1991 final rule established that care associated with certain Group ''C'' cancer drugs and treatment INDs could be covered, while the treatment IND itself could not. The 1991 rule placed these provisions in § 199.2, under the definitions for ''experimental'' and ''prescription drugs and medicines,'' with the prescription drugs and medicines provision repeated in § 199.4. That rule concluded that any use of a drug that had not been approved for general use by the FDA was necessarily experimental and could not be covered. In a final rule published January 6, 1997 (62 FR 625), the DoD issued clarifying language regarding the exclusion of unproven drugs, devices, and medical treatments and procedures. The requirement for FDA approval of drugs remained, though the definition of experimental was removed from § 199.2, and the language in § 199.4 was substantially revised. However, none of those changes had a substantive impact on coverage criteria. FDA approval remained a key requirement for coverage of drugs, and treatment INDs could not be covered although care associated with them could be covered. Since that time, no significant changes have been made to TRICARE regulations that would impact the FDA-approval requirement for drugs, or the exclusion of cost-sharing treatment INDs. Importantly, no changes have been made to the DoD's statutory authority for coverage of care under TRICARE, which mandates that such care be medically necessary in order to be eligible for TRICARE coverage. The statutory provision concerning medical necessity (10 U.S.C. 1079(a)(12)) specifically exempts care provided in certain NIH clinical trials (in which investigational drugs are often administered). Because Congress specifically carved out circumstances under which drugs and other treatments not otherwise coverable were permitted to be cost-shared, the Department has historically read the statute to mean that the carve-out represents the only exemption Congress intended to make for TRICARE coverage in investigational settings. Based on this interpretation, the DoD finds that Congress did not intend for the DoD to include unproven care in its coverage of medically necessary care.

In evaluating whether it would be appropriate for TRICARE to cost share investigational drugs authorized for treatment use under EA programs, the DoD next evaluated changes to FDA's regulation of its EA programs to determine if those changes were such that this care could be considered medically necessary under TRICARE. The FDA first formalized the treatment use of investigation drugs on May 22, 1987 (52 FR 19466), in a final rule that included the establishment of treatment INDs. The DoD's 1991 rule published after that rule, and the DoD found that treatment INDs were unproven and, thus, could not be covered under its statutory authority. The FDA revised its regulations authorizing the treatment use of investigational drugs in a final rule establishing its EA programs, which published on August 13, 2009 (74 FR 40900). FDA's rule was published under new authority granted by Congress in the FDA Modernization Act of 1997 (Pub. L. 105–115), which contained provisions specific to expanding access to treatment use of investigational drugs. In the final rule implementing its EA programs, the FDA established three categories of treatment uses of investigational drugs: single patients, including for emergency use; intermediate-size patient populations; and treatment INDs or treatment protocols. Each category of EA established criteria for authorization, with single patient access requiring the lowest level of evidence and treatment INDs and treatment protocols requiring the highest levels of evidence. The evidence for treatment INDs was not substantially different than it was in the earlier 1987 rule.

According to 21 CFR 312.320, established by the 2009 final rule, in order for the FDA to authorize a treatment IND or protocol for the treatment of a serious disease or condition, there must be ''sufficient clinical evidence of safety and effectiveness to support the [EA] use.'' The FDA states this would ordinarily be data from a Phase III trial, though compelling data from completed Phase II trials may be used. Section 312.320 further states that when the treatment IND or protocol is for a life-threatening disease or condition, ''the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug may be effective and would not expose patients to an unreasonable and significant risk of illness or injury.'' The FDA expects this level of evidence would typically come from Phase III or Phase II trials but could be based on more preliminary clinical evidence. Additionally, in its preamble to the 2009 final rule, the FDA acknowledges ''that drugs made available under expanded access programs are typically investigational'' (74 FR 40907) and that ''it is likely that some drugs made available for treatment use will ultimately be shown to have no benefit, and in fact cause harm'' (74 FR 40911). Further, all EA drugs require an Institutional Review Board (IRB) review, similar to such reviews for clinical trials, underlining the unproven nature of these drugs.

Although the DoD appreciates the value of early access to drugs for patients with serious or life-threatening diseases, the DoD does not have the statutory authority that would allow it to permanently cover investigational therapies, even for severe illnesses. The level of evidence required by the FDA for widespread treatment use of INDs, the most stringent evidence requirement of the three EA drug categories, is insufficient to meet the DoD's statutory requirement for medically necessary care, as implemented through the regulation excluding unproven care at 32 CFR 199.4(g)(15) from TRICARE coverage as determined by a review of the available literature that falls under the categories of the hierarchy of reliable evidence in § 199.2. The DoD lacks statutory authority to treat serious or life-threatening diseases differently than other diseases when determining medical necessity. In fact, the rule that formalized the criteria for a treatment to be considered ''proven'' was prompted by a treatment for life-threatening breast cancer. The therapy in question, high dose chemotherapy with stem cell rescue, was seen by some in the medical community at the time as the best and only treatment available to patients with certain types of breast cancer resistant to other treatments. However, the DoD excluded coverage due to lack of evidence of efficacy and the presence of evidence that the therapy may actually cause harm. Over 25 years later, the therapy remains unproven and is excluded from coverage under TRICARE. The DoD noted in the 1997 rule that the purpose of its process for determining whether care should be covered is ''to prevent CHAMPUS

beneficiaries from being exposed to less than fully developed and tested medical procedures and to avoid the associated risk of unnecessary and unproven treatment'' (62 FR 628). Based on the above analysis, investigational drugs authorized for treatment use by the FDA must continue to be excluded under the TRICARE Program.

While the DoD cannot permanently cover investigational drugs authorized by the FDA for treatment use, care associated with these therapies may continue to be covered when long-standing program requirements are met: (1) that the patient's medical condition warrants the treatment, and (2) the care is provided in accordance with the generally accepted standards of medical practice. The DoD is updating the regulation to clarify that this care may be covered for any investigational drug authorized for treatment use by the FDA under its EA programs, not just treatment INDs (*i.e.,* this coverage applies also to single-patient use, including emergency access, and intermediate access). This clarification is not a change in coverage, as the DoD has long interpreted the regulation regarding care associated with treatment INDs to include the other categories of EA treatment uses.

Establishing a TRICARE Clinical Trial Benefit for Infectious Disease Health Emergencies

Second, this final rule authorizes coverage of services and supplies provided in conjunction with Phase I, II, III, and IV clinical trials sponsored or approved by any NIH Center or Institute other than the NIH Clinical Center for the treatment or prevention of an infectious disease that results in a Government-recognized infectious disease health emergency, rather than only covering NIAID-sponsored studies for the treatment or prevention of COVID–19. In this context, a Government-recognized infectious disease health emergency means that the President of the United States has declared a national emergency, or the HHS Secretary has declared a PHE for a pandemic or epidemic that occurs as a result of an infectious disease. For care rendered overseas (defined as locations outside of the 50 United States and the District of Columbia) to TRICARE beneficiaries, this definition also includes epidemics and pandemics recognized by foreign governments and by the World Health Organization, although only NIH-approved clinical trials in the region experiencing the Government-recognized epidemic or pandemic qualify for TRICARE coverage. An NIH-approved clinical trial means a clinical trial for which NIH, including an NIH Center or Institute, serves as a collaborator, as the term ''collaborator'' is defined by NIH.[1] At the time this rule's publication, NIH defines a collaborator as ''An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.'' As 10 U.S.C. 1079(a)(12) requires clinical trials covered under the TRICARE program to be either NIH-sponsored or NIH-approved, but does not define the term ''NIH-approved,'' the DoD finds it appropriate to use the current NIH definition of ''collaborator'' as meaning ''NIH-approved'' when an NIH Center or Institute is listed as a collaborator for a clinical trial that is otherwise eligible for TRICARE coverage. Should NIH update this definition or cease listing collaborators, the DoD would determine if a change in TRICARE regulation would be beneficial to TRICARE's beneficiary population and, if so, make appropriate changes through rulemaking. The National Library of Medicine's registry of clinical trials, available from *https://www.ClinicalTrials.gov* at the time of this final rule's publication, lists information about trials, including sponsors and collaborators. These changes will ensure that TRICARE beneficiaries receive access to all clinical trials sponsored or approved by NIH Centers or Institutes for the treatment or prevention of infectious diseases associated with Government-recognized infectious disease health emergencies, including COVID–19, not only NIAID-sponsored clinical trials studying the treatment or prevention of COVID–19. In the absence of this change, beneficiaries may opt not to participate in COVID–19 clinical trials sponsored or approved by other NIH Centers and Institutes due to the potential for large out-of-pocket costs when they would have participated had TRICARE covered these costs. Many of these NIH Centers and Institutes study specific organ systems or areas of research (*e.g.,* diabetes and aging), and COVID–19 clinical trials sponsored or approved by these Centers and Institutes tend to study the short-term and long-term impact of COVID–19 in these specific areas of research, including specific short-term and long-term health problems caused by COVID–19, whereas NIAID COVID–19 clinical trials tend to study the virus and disease as a whole.

COVID–19 patients experience increased risk of complications such as severe fatigue and muscle weakness, anosmia and ageusia (*i.e.,* loss of taste and smell), dyspnea (*i.e.,* difficulty breathing), cognitive impairment, encephalitis, pneumonia, acute respiratory distress syndrome, acute liver injury, acute myocardial injury, cytokine storms, and stroke during or shortly after infection and recovery. Long-term or chronic health consequences (*i.e.,* sequelae) of COVID–19 are often referred to as ''long COVID'' and include myocarditis, multisystem inflammatory syndrome, autoimmune disorders, venous thromboembolism, diabetes mellitus, Guillain-Barre syndrome, kidney damage, lung damage, and psychiatric disorders. These short-term and long-term complications impact both individual and population health. For example, health systems, providers, and public health officials must prepare to treat and mitigate higher rates of pulmonary, cardiovascular, and kidney disease and to prevent, diagnose, and treat these conditions in populations not previously thought to be higher risk.

In addition, this change will not expire upon the termination of the President's declared national emergency for COVID–19, as is stated in the IFR published by the DoD on October 30, 2020 (85 FR 68753–68758). Continuing to cover services and supplies provided in conjunction with NIH-sponsored or approved Phase I, II, III, and IV clinical trials for the treatment or prevention of COVID–19 will ensure that TRICARE beneficiaries have the ability to participate in COVID–19 clinical trials after the termination of the national emergency without fear of significant out-of-pocket costs. Due to the novel nature of COVID–19 and the large number of COVID–19 cases since the advent of the pandemic, it is crucial that researchers continue to study treatments (including preventive treatments) for the disease and short-term and long-term health impacts of the disease and its treatments in order to improve treatment for individuals with complications from COVID–19; to better support population health efforts (*e.g.,* chronic disease management and identification of high-risk patients); and to better prepare public health experts and clinicians to mitigate future diseases and pandemics. Likewise, TRICARE coverage of clinical trials investigating treatments for and prevention of future infectious diseases that are associated with Government-recognized health emergencies will allow TRICARE to quickly and efficiently maximize beneficiary access to emerging treatments in the event of

[1] *https://clinicaltrials.gov/study-basics/glossary.*

future epidemics and pandemics, as well as support the societal need for research into emerging treatments and preventive medicine, including vaccinations.

These changes will greatly expand beneficiaries' access to clinical trials beyond the termination of the President's national emergency and will further DoD support of research studying COVID–19 and other infectious diseases that may cause a pandemic or an epidemic, including investigating treatments to improve the long-term prognosis or symptoms in sufferers of the disease.

Establishing a TRICARE Clinical Trial Benefit for Severely Debilitating Conditions, Life-Threatening Conditions, and Rare Diseases

Lastly, this final rule authorizes coverage of services and supplies provided in conjunction with Phase I, II, III, and IV clinical trials sponsored or approved by any NIH Center or Institute (except the NIH Clinical Center, which already provides all care free of charge to participating patients) for which the clinical trial studies a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition is severely debilitating, life-threatening, or a rare disease. This provision modernizes the TRICARE benefit by expanding existing coverage of clinical trials and will result in increased access to emerging therapies for beneficiaries with serious conditions and ineffective or no viable treatment options. This change will also add coverage of Phase IV NCI-sponsored and approved clinical trials and remove existing requirements specific to Phase I NCI clinical trials to maintain parity between the clinical trial benefits. TRICARE's Phase I-specific requirements are no longer necessary, as requirements in this final rule and changes to how Phase I clinical trial protocols are approved result in the existing Phase I requirements being duplicative, which may also duplicate administrative costs and increase patient, provider, and Government burden without any improvement to patient safety or access to eligible clinical trials. Phase IV trials are critical in continuing to assess a treatment's safety and efficacy, especially safety and efficacy within specific sub-populations and in conjunction with certain drugs, even after the treatment is FDA-approved.

As used in this provision, ''uncontrolled'' refers to a symptom or aspect of a specific condition that cannot be effectively managed or cured with existing medications, durable medical equipment, surgery, or other therapies. This can mean, for example, that an existing treatment has a high likelihood of harmful side effects experienced by a significant proportion of patients, including chemical dependence, elevated risk of mortality, or teratogenic effects. It can also mean that the existing treatment has a relatively miniscule probability of successfully treating a specific condition or is only palliative in nature. It does not mean that harmful side effects have the potential to occur with a specific treatment or that a specific treatment has a possibility of failure.

A ''rare disease'' refers to any disease or condition that has a prevalence of fewer than 200,000 persons in the United States; TRICARE already uses this definition for regulatory and policy requirements specific to rare diseases. ''Severely debilitating'' is defined as ''diseases or conditions that cause major irreversible morbidity'' and ''life-threatening'' is defined as ''diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.'' The FDA uses both definitions in 21 CFR 312.81 for classifying treatments, developing clinical trials and emergency use requirements, and creating drug development guidelines. As the FDA is directly involved in the regulation and approval of new drugs and devices, the DoD finds it appropriate to use the FDA's definitions to determine which clinical trials are most appropriate to cover in writing this rule and to determine which clinical trials will be eligible for coverage under this rule. While the DoD is mirroring the FDA's definitions in implementing these provisions, the DoD's determination that these categories of diseases and corresponding definitions should be included under the TRICARE clinical trial benefit is based on the Department's evaluation of the needs of the TRICARE beneficiary population. Should the FDA update either definition, the DoD would evaluate the changes to determine if a similar change in TRICARE regulation would be beneficial to TRICARE's beneficiary population and, if so, make appropriate changes through rulemaking.

Severely debilitating conditions may have existing treatments that manage certain aspects of the condition but have no curative treatments for aspects of the disease that severely decrease the patient's health and quality of life. New clinical trials generally seek to improve upon existing treatments by improving patient outcomes, reducing side effects, or improving cost efficiency. Examples of severely debilitating conditions include Canavan Disease and Cystic Fibrosis. Like severely debilitating conditions, many life-threatening diseases have existing treatments, but these treatments may increase expected life expectancy for patients with the disease while resulting in serious side effects or not curing the disease (*e.g.,* open surgery to treat cardiovascular diseases, thrombolytics or anticoagulants to treat blood clots, insulin injections for diabetes); provide a chance of remission or disease reversal but not restore life expectancy in all patients (*e.g.,* chemotherapy); or manage symptoms associated with the disease but not increase life expectancy (*e.g.,* treatments for Alzheimer's Disease). Examples of life-threatening diseases include Hepatic Encephalopathy and Amyotrophic Lateral Sclerosis. Researchers conducting clinical trials on treatments for rare diseases experience difficulty in recruiting sufficient patient sample sizes, so it is especially important that TRICARE facilitate beneficiary participation in rare disease trials. Examples of rare diseases include Acquired Hemophilia and Guillain-Barré Syndrome. Many diseases may fall into multiple categories; for example, many rare diseases such as Duchenne Muscular Dystrophy and Creutzfeldt Jakob Disease are also severely debilitating and life-threatening. These examples are used in the context of the time of this rule's publication with the understanding that treatments for these conditions may advance over time. Additionally, these clinical trials may involve participation by vulnerable populations, such as children and pregnant individuals. As this benefit is not intended to influence beneficiaries into participating or not participating in a clinical trial, only to remove financial barriers to participation for certain clinical trials, the Department emphasizes that IRB approval and full informed consent for patients continues to be required for these clinical trials. When appropriate, the Director, DHA, may issue additional requirements for these populations in TRICARE's implementing instructions.

Requirements for TRICARE coverage of these clinical trials are similar to existing requirements for the COVID–19 and cancer clinical trial benefits, namely that TRICARE will cost-share all routine medical care and testing required for participation in the clinical trial; that participants meet entry criteria for said protocol; that providers

rendering care as part of the clinical trial be TRICARE-authorized providers; that TRICARE will not cover care rendered in the NIH Clinical Center or costs associated with non-treatment research activities; and that cost-shares and deductibles apply to TRICARE coverage of clinical trials. Like the COVID–19 and cancer clinical trial benefits, this provision also does not permit coverage of any services or supplies that are already covered under the investigational protocol, including the treatment being studied through the clinical trial. For example, TRICARE will not reimburse costs for a biologic used in clinical trials testing the efficacy of that biologic. Only routine care, meaning those supplies and services that TRICARE otherwise would have covered during the normal course of treatment (including costs for screening tests to determine clinical trial eligibility), will be eligible for coverage. Routine care includes services such as examinations, imaging, and blood tests to monitor or assess patient health during the clinical trial and supplies such as drugs that TRICARE would cover in the absence of the clinical trial that are medically necessary to treat side effects associated with the treatment under study in the clinical trial. Routine care may differ in frequency and magnitude than care would have otherwise in the absence of the investigational treatment. For example, a patient with lung cancer might receive monthly blood tests as part of a standard treatment but require weekly tests while undergoing an investigational treatment that is part of an eligible clinical trial to monitor adverse events. To further distinguish between coverage of routine services and supplies and other services and supplies provided as part of a clinical trial, this final rule amends § 199.4(g)(14) to clarify that the exclusion of ''services and supplies provided as a part of or under a scientific or medical study, grant, or research program'' does not apply to routine services and supplies provided in conjunction with clinical trials as authorized in § 199.4(e)(26). The exclusion still applies to non-routine services and supplies provided under clinical trials subject to § 199.4(e)(26), *e.g.,* the investigational treatment being studied within the clinical trial. However, TRICARE may cover treatments for complications (*i.e.,* unfortunate sequelae) related to unproven care, including care received as part of a clinical trial eligible under this benefit, as authorized in § 199.4(e)(9). Lastly, as with the COVID–19 and cancer clinical trial benefits, this provision authorizes the Director, DHA, to issue procedures and guidelines regarding the administrative process by which individual patients may be eligible for this benefit. Additional examples of requirements for the types of clinical trials, conditions, and routine costs eligible for coverage under this change to the TRICARE benefit will be detailed in the TRICARE implementing instructions (*i.e.,* the TRICARE manuals), which are available at *https://manuals.health.mil/* at the time of this final rule's publication.

All provisions of this final rule support NIH research by expanding the potential pool of patients who can participate in clinical trials for emerging treatments and expand TRICARE beneficiary access to emerging treatments and therapies for serious conditions. Participation of patients in clinical trials is crucial to the development of new treatments, particularly for conditions with few or no effective existing treatments. Patients with severely debilitating, life-threatening, or rare conditions may also seek early access to investigational treatments by participating in clinical trials, which may improve their symptoms, quality of life, and/or prognosis. While participation in clinical trials must always be voluntary and participants must be provided with full and informed consent, it is likewise critical that beneficiaries with severely debilitating, rare, or life-threatening conditions have access to and choice in available potential treatments offered through clinical trials in order to maximize their opportunity to receive available treatments, especially when the standard treatment may not successfully treat or cure the condition, or when no treatment exists. The provisions in this final rule provide additional options for and access to emerging treatments for these beneficiaries by decreasing some financial barriers to clinical trials. The Department initially established a demonstration to test the benefits and feasibility of the NCI cancer clinical trials benefit, which subsequently became a permanent benefit through rulemaking. Due to the success of that demonstration at expanding access to emerging treatments and the similarities to the types of conditions eligible under this final rule (*i.e.,* like cancer, such conditions are likewise severely debilitating, life-threatening, and/or rare diseases), the Department finds that an initial demonstration for this benefit is unnecessary and that promulgating a permanent benefit for clinical trials studying emerging treatments for these conditions under the requirements specified in this final rule will provide beneficiaries with the most efficient access to emerging treatments in the safest manner possible.

The DoD also acknowledges that clinical trial participation carries risks as well as benefits and therefore this final rule includes several components to protect patients while offering expanded coverage for clinical trials. First, the Department is limiting the clinical trial benefit to those trials studying new treatments or treatments for an uncontrolled symptom or aspect of conditions that are severely debilitating, life-threatening, and/or a rare disease. This will ensure that the DoD is only covering care that beneficiaries could not receive in the absence of the clinical trial and that may improve their symptoms or prognosis. Second, clinical trials eligible for DoD coverage must be sponsored or approved by an NIH Center or Institute. This provision, which is also required in the statutory authority for coverage of clinical trials at 10 U.S.C. 1079(a)(12), will ensure that covered clinical trials meet conventional ethical, safety, quality, and general Good Clinical Practice standards, such as IRB approval and informed consent for all participants. Lastly, Phase 0 clinical trials (exploratory IND studies that assess pharmacokinetics and pharmacodynamics) will not be eligible for coverage. TRICARE coverage of routine services associated with clinical trials that meet these standards will be the safest way for beneficiaries to pursue emerging treatments.

*B. Legal Authority*

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/.*

*C. Community Impact*

Beneficiaries who enroll in NIAID-sponsored COVID–19 clinical trials after the expiration of the COVID–19 national emergency will benefit from TRICARE continuing to reimburse costs for services and supplies provided in conjunction with eligible clinical trials, instead of having to pay for these costs out-of-pocket. Likewise, under the new provisions within this final rule, beneficiaries who enroll in future COVID–19 clinical trials sponsored or approved by other NIH Centers and Institutes will also be able to participate in such trials without paying for costs related to the clinical trials out-of-

pocket. In the event of a future pandemic or epidemic, TRICARE beneficiaries will benefit from being able to enroll in clinical trials studying the treatment or prevention of the infectious disease causing the Government-recognized infectious disease health emergency.

This final rule also expands clinical trial coverage to services and supplies provided in conjunction with clinical trials that are sponsored or approved by NIH Centers and Institutes and that involve a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition for severely debilitating, life-threatening, and rare diseases. TRICARE beneficiaries with a severely debilitating or life-threatening condition, or who have a rare disease, will benefit from the ability to enroll in clinical trials studying investigational treatments for their condition without worrying about paying for significant medical costs related to the clinical trial out-of-pocket. This final rule will also positively impact research institutions, including NIH Centers and Institutes, by improving access for these beneficiaries to participate in valuable research, which expands the participant pool for clinical trials; this research will likewise benefit the public, who may be able to access emerging treatments for a severely debilitating, life-threatening, or rare disease depending on the results for each clinical trial. The public may also benefit from improved treatment of these conditions, which often result in higher rates of disability and lower life expectancy. Lastly, this final rule will impact the TRICARE managed care support contractors, who will be responsible for ensuring the requirements set out in these provisions are met. DHA will delineate the full extent of these responsibilities in contract modifications.

*D. Regulatory History*

Each of the sections under which TRICARE is administered are revised periodically to ensure requirements continue to align with the evolving health care field. The DoD most recently updated 32 CFR 199.4 on June 1, 2022 (87 FR 33001) by permanently adopting coverage of telephonic services. The coverage of care associated with treatment INDs in the second paragraph of the note to § 199.4(g)(15)(A)(i) has not been permanently revised since the 1997 final rule (62 FR 625) discussed earlier in this final rule, which clarified the coverage criteria for proven therapies under TRICARE to include that treatment INDs were not eligible for coverage but care associated with their administration could be covered when certain criteria were met. The clinical trials provision modified in this final rule last changed due to the IFR establishing the COVID–19 clinical trial benefit (85 FR 68753–68758).

## II. Regulatory Impact Analysis

*A. Baseline*

TRICARE covered investigational drugs for treatment use when authorized by the FDA under its EA programs through a previous IFR; this coverage was temporary, limited to treatments of COVID–19, and expired upon the termination of the President's national emergency for COVID–19 on April 10, 2023. The FDA granted emergency use authorization for several COVID–19 therapies such as Remdesivir shortly after their initial authorization under FDA EA programs, and therefore TRICARE coverage of EA drugs has been very limited. Likewise, Government costs due to coverage of EA treatments have been minimal. Due to a lack of statutory authority to continue the benefit in perpetuity or to expand it for treatments other than COVID–19, the DoD is not considering continuing or expanding coverage of EA treatments in the potential courses of action below.

TRICARE also currently covers routine costs associated with Phase I, II, and III NCI-sponsored Cancer Clinical trials and Phase I, II, III, and IV clinical trials sponsored by NIAID for the treatment or prevention of COVID–19. TRICARE coverage of routine costs associated with the current clinical trial benefit, which includes NCI-sponsored Phase I, II, and III Cancer Clinical Trials, is estimated to cost $18.0M in Fiscal Year 2022 (FY22), and we estimate that this baseline cost will increase by 4.5% annually to $20.4M in FY24. These estimates were calculated using historical expenditures, current NCI clinical trials available from ClinicalTrials.gov, and projections of increases for medical costs and beneficiary demand.

TRICARE coverage of NIAID-sponsored COVID–19 clinical trials also expired upon the termination of the President's national emergency for COVID–19, although this final rule resumes coverage for NIAID-sponsored COVID–19 clinical trials starting on the final rule's effective date. Because this rule published after the termination of the national emergency, all costs related to COVID–19 clinical trials will represent incremental costs to the Government, but costs associated with NIAID-sponsored COVID–19 clinical trials are included here as baseline costs to distinguish them from the costs associated with other clinical trials. Upon examining TRICARE Encounter Data (TED) Records through July 2022, only two claims exist for TRICARE beneficiaries participating in NIAID-sponsored COVID–19 clinical trials; both claims totaled $28,683 over a 22-month period, equaling an average of $1,366 per month, or an expected average annual cost of $16,392 in FY22. Using the expected value approach, we anticipate that the Government will incur this monthly cost, on average, in the future. This low utilization is likely because most COVID–19 clinical trials were fully funded by sponsors and therefore no claims were filed for other TRICARE beneficiaries participating in COVID–19 clinical trials; therefore, we anticipate that $1,366 per month is likely over-estimating actual baseline costs.

*B. Coverage of Government-Recognized Health Emergency Clinical Trials and Select NIH-Sponsored or Approved Clinical Trials*

The DoD's final regulation expands TRICARE's clinical trial benefit to (1) make the coverage of NIAID-sponsored COVID–19 clinical trials permanent and cover all NIH-sponsored or approved COVID–19 trials; (2) expand coverage of NCI Cancer clinical trials to include Phase IV trials and NCI-approved Cancer clinical trials; (3) cover services and supplies provided in conjunction with Phase I, II, III, and IV clinical trials sponsored or approved by any NIH Center or Institute for the treatment or prevention of an infectious disease that results in a Government-recognized infectious disease health emergency, as defined above in the Statement of Need for this Rule section; and (4) cover services and supplies provided in conjunction with Phase I, II, III, and IV clinical trials sponsored or approved by any NIH Center or Institute in which the clinical trial studies a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition is severely debilitating, life-threatening, or a rare disease, as these terms are defined in this final rule. This expansion of clinical trial benefits creates several requirements for coverage of each type of trial.

Through this final rule, current coverage of COVID–19 clinical trials becomes permanent and is further expanded with coverage of NIH-sponsored and approved clinical trials for treatment or prevention of COVID–19, rather than NIAID-sponsored clinical trials only. This final rule also broadens the benefit in anticipation of

future infectious diseases that result in a pandemic or epidemic and result in the declaration of a national emergency or PHE. Additionally, this final rule expands coverage of NCI Cancer clinical trials to include NCI-approved Cancer clinical trials and Phase IV clinical trials, and adds coverage for clinical trials for severely debilitating, life-threatening, and rare diseases. Coverage requirements will reflect those currently in effect for NIAID-sponsored COVID–19 clinical trials. For example, the clinical trial must study a specific treatment (including preventive treatments) rather than the infectious disease or population health in general, and TRICARE will only cover routine costs associated with eligible clinical trials (*e.g.,* TRICARE will not reimburse the cost of an investigational drug or new imaging method). These clinical trials may study treatments for short or long-term health complications from the infectious disease, as well as treatments that prevent the infection or transmission of a contagion that causes the infectious disease.

This targeted approach greatly expands the clinical trial benefit to NIH-sponsored or approved Phase I, II, III, and IV clinical trials while specifying TRICARE's clinical trial benefit by imposing requirements on the types of eligible treatments (*i.e.,* the clinical trial study of a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition) and types of eligible diseases and conditions (*i.e.,* those that are severely debilitating, life-threatening, or a rare disease). In this rule, a severely debilitating disease is defined as causing major irreversible morbidity; a life-threatening disease is defined as a disease or condition where the likelihood of death is high unless the course of the disease is interrupted or a disease with potentially fatal outcomes in which the end point of clinical trial analysis is survival; and a rare disease is defined as having a prevalence of fewer than 200,000 persons in the United States. Definitions for ''severely debilitating conditions'' and ''life-threatening conditions'' will be added to 32 CFR 199.2, as well as definitions for ''NIH-sponsored clinical trial'' and ''NIH-approved clinical trial.'' Additional discussion and examples of eligible treatments and diseases are provided earlier in the Background section of this preamble.

In addition to these changes, the termination of coverage of EA treatments for COVID–19 is also discussed in this rule. An in-depth analysis of this decision is discussed in the Background section of this preamble.

1. Analysis of Final Regulation

By (1) making the coverage of NIAID COVID–19 clinical trials permanent and covering all NIH-sponsored or approved COVID–19 trials, beneficiaries would be able to enroll in any NIH-sponsored or approved COVID–19 clinical trial for the treatment or prevention of COVID–19 after the termination of the President's national emergency for COVID–19 and be eligible for coverage of routine costs associated with such trials. Clinical trials studying treatments for short- or long-term health complications (*i.e.,* sequelae) caused by COVID–19 would also be eligible for coverage under this benefit (*e.g.,* a clinical trial studying a new oral steroid to treat Acute Respiratory Distress Syndrome caused by COVID–19 pneumonia would be eligible for coverage). Clinical trials that are solely observational or that are not studying a specific drug, vaccine, device, or other treatment would continue to be ineligible for coverage. Other coverage requirements would mirror existing regulatory requirements for NIAID COVID–19 clinical trials. For example, clinical trials conducted at the NIH Clinical Center would be ineligible for TRICARE coverage of any costs. Requirements for (2) Phase IV Cancer clinical trials will largely mirror existing regulatory requirements for NCI Cancer clinical trials, including requiring pre-authorization before the initial evaluation; requiring that providers be TRICARE-authorized; requiring that care rendered in the NIH Clinical Center be excluded from coverage; and applying normal cost-share procedures.

Additionally, this final rule financially supports clinical trial research sponsored or approved by any NIH Center or Institute for the (3) prevention and treatment for future Government-recognized infectious disease emergencies, as well as for (4) severely debilitating, life-threatening, and rare diseases. It also improves access to treatments for such diseases in the safest manner possible for TRICARE beneficiaries with the greatest need for emerging treatments, *i.e.,* beneficiaries with severely debilitating, life-threatening and rare conditions when the treatment has limited efficacy or when no treatment exists. These treatments may significantly improve beneficiary health outcomes (including symptoms, quality of life, prognosis, and life expectancy), and support of this research may assist with the full approval of emerging treatments, which would also improve the health outcomes for the general public and may reduce public and private spending due to death and disability that result from these conditions. Through expanded coverage for routine costs, clinical trials may receive higher application rates from TRICARE beneficiaries. Additionally, many groups are underrepresented in clinical trials research; this expansion in access may contribute to increased diversity within the clinical trial sample population. As discussed above, both factors are necessary to determine the actual efficacy of a treatment, especially across sub-populations (*e.g.,* is a treatment less effective for men over the age of 75 or more effective for female Indigenous Americans). For Phase IV trials studying a treatment already covered by TRICARE, the Government may realize cost-savings by paying for routine costs only, rather than also paying for the treatment. Likewise, the Government may realize cost savings from beneficiaries receiving an experimental treatment through a clinical trial, which is paid for by the investigator, over potentially less effective treatments covered by the TRICARE Program. This is especially relevant for novel infectious diseases such as COVID–19, which have few non-investigational treatments for short-term or long-term complications from the disease. Continuing the COVID–19 clinical trial benefit and expanding it to future infectious diseases that result in a pandemic or epidemic to the extent that a national emergency or PHE is declared will also support the development of treatment options for individuals who experience these complications.

The Government-recognized infectious disease health emergency clinical trial benefit, including continued coverage of COVID–19 clinical trials, will also support research efforts that may mitigate future pandemics and epidemics, including the development of treatments (as well as vaccines or other preventive treatments) for future novel infectious diseases and their associated short-term and long-term complications. While most of these benefits are intangible or otherwise infeasible to quantify, this benefit is also expected to save beneficiaries who were otherwise inclined to participate in a particular clinical trial hundreds to thousands of dollars per trial, although this amount is highly variable based on the specific type of trial. This cost is transferred from TRICARE beneficiaries participating in clinical trials to the Government and is further discussed in the cost analysis below.

As participation in this benefit is optional for clinical trial investigators, providers, and beneficiaries, this change imposes no direct burden on the public, but the pre-authorization requirement for clinical trials studying treatments for severely debilitating, life-threatening, or rare diseases will impose a minor barrier to this benefit. Pre-authorization provides some assurance that the beneficiary will not be financially liable for routine care provided under the trial. The Department finds that pre-authorization is necessary to ensure that these clinical trials meet all requirements set forth in this rule and does not anticipate pre-authorization imposing a significant burden, as most clinical trials require months to years to complete recruitment and enrollment, and a significant number of clinical trials for these categories of diseases utilize rolling enrollment. Additionally, TRICARE coverage of NCI Cancer Clinical Trials currently requires pre-authorization, and many treatments for severely debilitating, life-threatening, and rare diseases likewise have existing pre-authorization requirements under public and private health insurance plans. This requirement will also impose administrative costs to the Government; these costs are discussed in this analysis. TRICARE coverage of clinical trials studying treatments for Government-recognized infectious disease health emergencies will continue to not require pre-authorization due to the emergent, fast-paced, and novel nature of infectious diseases that cause pandemics and epidemics.

As discussed above, coverage of clinical trials carries risks to beneficiaries, who may experience mild or severe adverse events due to clinical trial participation or who may be randomly assigned to the control group. However, this rule limits eligible clinical trials to those studying a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition is severely debilitating, life-threatening, or a rare disease. These requirements therefore restrict the TRICARE clinical trial benefit to those beneficiaries in the greatest need of emerging treatments. Additionally, pursuing emerging treatments provided under an NIH-sponsored or approved clinical trial generally carries less risk to patients than unproven treatments pursued outside of clinical trial protocols due to the safety parameters required by NIH-sponsored or approved clinical trial protocols and requirements, such as IRB approval and informed consent for all patients. The Background section of this preamble further discusses patient protection.

As discussed in the baseline cost section, we estimate average annual costs at $16,392 for FY22 for NIAID-sponsored COVID–19 clinical trials. Due to low utilization and because COVID–19 clinical trials sponsored or approved by non-NIAID NIH Centers and Institutes tend to incur similar or lower costs than NIAID-sponsored COVID–19 clinical trials, we assume that costs for all NIH-sponsored or approved COVID–19 clinical trials will not exceed those for NIAID-sponsored COVID–19 clinical trials. However, we estimate a potential increase in demand and medical costs, so we projected a 4.5% increase in costs annually. Therefore, we estimate costs to be $18,704 in FY24 and estimate 5-year costs to be $102,323 from FY24–FY28. We estimate no incremental start-up or incremental administrative costs, as any administrative requirements (*e.g.,* eligibility determinations and customer support) are within the existing scope of the Managed Care Support contracts, which have already been modified to include the COVID–19 clinical trial benefit.

To approximate TRICARE costs for NCI Phase IV trials, we used a cost ratio approach to calculate the relative costs of NCI Phase IV trials compared to NCI Phase I–III clinical trials. Direct costs to the Government were calculated by first analyzing historical TRICARE expenditures for NCI-sponsored Cancer Phase I, II, and III clinical trials from TED records, representing baseline costs for this rule ($18.0M in FY22). We chose this approach because NCI Phase IV clinical trial costs are an unknown variable, but we know TRICARE-specific costs for NCI-sponsored Phase I–III trials and total enrollment in NCI-sponsored clinical trials. To accomplish this, we first analyzed public data on ClinicalTrials.gov for active, non-recruiting NCI-sponsored or approved Phase I–IV clinical trials and identified the number of participants in each trial. Each trial was also classified into one of 11 categories representing various types of clinical trials and their associated costs, including a category that represented no costs. The historical TRICARE expenditures for the NCI Phase I–III trials were then used to calculate an annual average TRICARE cost per trial enrollee for each category; this average cost per enrollee for each specific category was also used to estimate TRICARE costs for the NCI Phase IV trials. This estimate, therefore, assumes that the average cost per enrollee will be the same from NCI Phase I–III to NCI Phase IV trials in a given category, as there is no other visibility into NCI Phase IV clinical trial costs. For example, we assume that an NCI Phase IV clinical trial studying a pharmaceutical drug would incur the same costs, on average, as an NCI Phase I, II, or III clinical trial studying a pharmaceutical drug.

The annual average TRICARE cost per trial enrollee for each category was then multiplied by the total number of non-NCI, non-COVID–19 clinical trial enrollees in each category (as reported on ClinicalTrials.gov) to estimate total costs for each category. Costs were calculated separately for Phase I–III and for Phase IV trials, and then Phase IV trial costs were divided by Phase I–III trial costs to calculate an estimated cost ratio of 3.53%, meaning that NCI Phase IV trial costs for all enrollees are 3.53% of the cost of non-NCI, non-COVID–19 Phase I–III trials for all enrollees. Note that these costs represent routine costs associated with clinical trials for all patients, not TRICARE beneficiaries alone, using TRICARE cost data from NCI clinical trials. This calculation is, therefore, not intended to estimate total NCI clinical trial costs for all participants. Instead, using this methodology provides an unbiased estimate of relative costs for NCI Phase IV trials compared to NCI Phase I–III clinical trials. To estimate incremental TRICARE costs for NCI Phase IV clinical trials, we multiplied the 3.53% cost ratio by the TRICARE costs for NCI Phase I, II, and III clinical trials, which equals $0.7M in projected FY24 costs for NCI Phase IV trials.

To estimate costs for coverage of Government-recognized infectious disease health emergencies, we first identified all national emergencies and PHEs due to infectious diseases within the last ten years. The Zika virus epidemic was declared a PHE on August 12, 2016, and lasted ten months. The mpox (initially referred to as monkeypox) outbreak was declared a PHE on August 2, 2022, and the PHE lasted nearly six months. The COVID–19 pandemic was declared a PHE on January 31, 2020, and a national emergency on March 13, 2020; the national emergency ended on April 10, 2023, and the PHE ended on May 11, 2023. Using historical data, we assume that the COVID–19 pandemic is a 100-year event, like the 1918 H1N1 flu pandemic. Additionally, using NIAID COVID–19 claims data and the total duration of the three Government-recognized infectious disease health emergencies in the United States from 2012 to 2022, we assume that expenditures for clinical trials will

average approximately $735 per month ($8,820 annually in 2022 dollars). Like other estimates discussed in this rule, we assume a 4.5% increase in costs annually, based on projections made by the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary. As with COVID–19 clinical trials, it is difficult to project the incidence and duration of future national emergencies and PHEs caused by pandemics and epidemics, as well as the number, duration, and type of clinical trials constructed to study each infectious disease and the participation in by TRICARE beneficiaries, so this estimate should be interpreted as an expected value over time. Therefore, we expect incremental Government costs of approximately $10,065 in FY24 and five-year costs of $55,063 from FY24–FY28.

We also used the same overall cost ratio methodology as the estimate for other NIH-sponsored or approved clinical trials to begin our estimate of covering the subset of NIH clinical trials that study severely debilitating, life-threatening, or rare diseases. After calculating costs for each category of clinical trial, we estimated the probability that each of the 556 clinical trials would meet eligibility criteria, *i.e.,* study a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition or the uncontrolled symptom of the condition under study in the clinical trial is severely debilitating, life-threatening, or a rare disease. The probabilities for each trial were multiplied by the average cost for that trial's category to estimate an expected value for the annual probability-adjusted costs for all participants. As discussed above, these costs represent Government costs for all participants if TRICARE had covered all routine costs; this calculation is also not intended to estimate total national costs for this subset of clinical trials. This methodology is instead intended to provide an unbiased estimate of relative costs to use in projecting TRICARE-specific costs for this subset of NIH clinical trials. Dividing the costs for NCI Cancer Phase I–IV clinical trials by the costs for this subset of NIH clinical trials resulted in a cost-adjustment ratio of 8.6%. In other words, we estimated that the costs of covering this subset of NIH clinical trials would be 8.6% of the costs of covering NCI Cancer Phase I–IV clinical trials. Multiplying this adjustment ratio by projected TRICARE costs for NCI Cancer Phase I–IV clinical trials equals an estimated TRICARE cost of $1.81M in FY24 to cover this subset of NIH clinical trials, including NCI-approved Cancer Phase I–III clinical trials. Adding this total to the costs of covering routine care associated with NCI Cancer Phase IV clinical trials ($0.72M), NIAID COVID–19 clinical trials ($0.02M), and Government-recognized health emergency clinical trials ($0.01M) equals a total estimated cost of $2.56M in FY24 to the Government for covering NIH-sponsored and approved clinical trials. We assume that these costs will increase 4.5% annually and project $14.00M in direct costs to the Government over five years from FY24–FY28.

Additionally, we anticipate administrative costs related to coverage of NIH-sponsored or approved clinical trials for severely debilitating, life-threatening, and rare diseases. Administrative costs represent the value of labor incurred by Government employees (including military and civilian DoD employees) and Government contractors (including sub-contractors) who administer the TRICARE benefit. One-time start-up costs and recurring administrative costs are therefore estimated at $445,510 and $88,344, respectively, in FY24; we also project a 4.5% increase in recurring administrative costs each following year. Start-up costs refer to resources used before implementing this final rule, including an impact assessment and development of requirements, administrative components, and information technology system changes. We project that approximately 1,810 full-time equivalent (FTE) hours will be required to implement all changes associated with this final rule, for an estimated one-time start-up cost of $445,510. For recurring resources required to implement these changes, we anticipate approximately one hour of labor per claim; this recurring labor includes care management, referral and pre-authorization requirements, eligibility reviews, and customer support. We assume no administrative costs will be incurred due to coverage of NIAID COVID–19 clinical trials or Government-recognized infectious disease health emergency clinical trials.

2. Total Costs for Government & Non-Government

This final rule impacts four direct medical cost components: (1) NIAID-sponsored and approved COVID–19 clinical trials, (2) NCI-sponsored and approved Cancer Phase IV clinical trials, (3) Government-recognized infectious disease health emergency clinical trials, and (4) other NIH-sponsored and approved clinical trials, which includes NCI-approved Cancer clinical trials. The subtotal for direct medical cost is estimated at $2.56M in FY24 and the five-year direct cost subtotal is estimated at $14.00M from FY24–FY28, assuming a 4.5% increase in costs annually based on projections made by the CMS Office of the Actuary. Costs for NCI-sponsored Cancer Phase I, II, and III trials are existing baseline costs and are therefore excluded. Start-up and recurring administrative costs for FY24 are estimated at $445,510 and $88,344, respectively, for a FY24 administrative cost total of $0.53M. Start-up costs are one-time costs occurring before the implementation of these provisions, while recurring administrative costs are projected to increase by 4.5% annually.

Table 1 summarizes the direct medical and administrative costs discussed above. These costs do not include any potential cost-savings, intangible benefits, or intangible costs to either the Government or non-Government entities. Additionally, healthcare providers and the general public are expected to incur zero costs, while costs to patients and Government contractors are transferred to the Government as direct medical costs or administrative costs, respectively.

TABLE 1—GOVERNMENT COSTS

[All costs in millions]

| | FY24 | FY25 | FY26 | FY27 | FY28 | FY24–FY28 |
|---|---|---|---|---|---|---|
| NIAID COVID–19 Clinical Trials | $0.02 | $0.02 | $0.02 | $0.02 | $0.02 | $0.10 |
| NCI Cancer Phase IV Clinical Trials | 0.72 | 0.75 | 0.79 | 0.82 | 0.86 | 3.94 |
| Government-recognized Health Emergency Clinical Trials | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.05 |
| Subset of NIH Sponsored and Approved Clinical Trials | 1.81 | 1.89 | 1.98 | 2.06 | 2.16 | 9.90 |

TABLE 1—GOVERNMENT COSTS—Continued

[All costs in millions]

| | FY24 | FY25 | FY26 | FY27 | FY28 | FY24–FY28 |
|---|---|---|---|---|---|---|
| Administrative Costs | 0.53 | 0.08 | 0.09 | 0.09 | 0.09 | 0.88 |
| Totals | 3.09 | 2.75 | 2.89 | 3.00 | 3.14 | 14.87 |

3. Benefits

Compared to the TRICARE baseline, this final rule provides greater assistance to federally funded or approved clinical studies. It also allows a greater number of beneficiaries to benefit from emerging treatments, and, based on public comments, the COVID–19 pandemic, and the clinical trials reimbursement landscape, the Department finds it appropriate to expand TRICARE's clinical trial benefit. Making the coverage of NIAID-sponsored COVID–19 clinical trials permanent and covering all NIH-sponsored or approved COVID–19 trials will further support scientific efforts into studying COVID–19, provide beneficiaries with access to emerging treatments for COVID–19 treatments that are not yet proven, and would remove some financial barriers for TRICARE beneficiaries who wish to participate in a clinical trial for an emerging treatment. Removing these financial barriers may encourage participation in NIH-sponsored or approved COVID–19 clinical trials over riskier, unproven treatments outside the safety parameters required by clinical trial protocols. Additionally, our targeted approach to expanded clinical trial coverage better protects patients by selecting certain diseases and conditions, as discussed above; patient safety is a key reason TRICARE generally only covers treatments proven safe and effective. As a Government-funded health program, TRICARE must also strive to use Government dollars in a cost-effective manner. The Department believes access to emerging, unproven treatments should be provided to beneficiaries who may substantially benefit from emerging treatments, namely beneficiaries with severely debilitating, life-threatening, or rare conditions for which treatments are limited, as well as conditions that result in epidemics or pandemics. Treatments for these conditions also tend to have limited reliable evidence and the Department's coverage of routine costs will further research into treatments for these conditions by improving beneficiary access to these clinical trials.

Additionally, the Patient Protection and Affordable Care Act (PPACA) requires health plans subject to PPACA requirements to cover routine patient costs for items and services furnished in connection with participation in the trials only if the clinical trial is federally approved or funded; studies the prevention, detection, or treatment of cancer or another life-threatening disease or condition; and either has an investigational new drug application or is exempt from investigational new drug application requirements. This rule, therefore, more closely aligns TRICARE's clinical trial benefit with clinical trial coverage offered by many private health plans. Ultimately, the DoD included these provisions to achieve a balance between assisting more beneficiaries—as well as the general public—at a lower cost to the Government while also protecting patient safety and ensuring that coverage of clinical trials is provided only to individuals who have a need for emerging treatments because they have a debilitating or life-threatening disease or condition or a rare disease.

## III. Regulatory Compliance Analysis

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

Executive Order 12866 and Executive Order 13563 direct agencies to assess all costs, benefits, and available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety effects, distributive impacts, and equity). These Executive Orders emphasize the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated not significant, under section 3(f) of Executive Order 12866.

*B. Executive Order 14192, ''Unleashing Prosperity Through Deregulation''*

This rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

*C. Congressional Review Act (5 U.S.C. 801 et seq.)*

Pursuant to the Congressional Review Act, this rule has not been designated a major rule, as defined by 5 U.S.C. 804(2).

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

The ASD(HA) certified that this 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.

*E. 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 1 year of $100 million in 1995 dollars, updated annually for inflation. This rule will not mandate any requirements for state, local, or tribal governments, and will not affect private sector costs.

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

It has been determined that this rule does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

*G. Executive Order 13132, ''Federalism''*

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This rule will not have a substantial effect on State and local governments.

*H. 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 final 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, Dental, Fraud, Health care, Health insurance, Individuals with disabilities, Mental health programs, and Military personnel.

For the reasons stated in the preamble, the DoD adopts the interim final rules amending 32 CFR part 199, which were published at 85 FR 54914–54924 on September 3, 2020 and 85 FR 68753–68758 on October 30, 2020 as final with the following changes:

## 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(b) by adding definitions for ''Life threatening conditions'', ''National Institutes of Health (NIH)-approved clinical trial'', ''NIH-sponsored clinical trial'', and ''Severely debilitating conditions'' in alphabetical order to read as follows:

**§ 199.2 Definitions.**

* * * * *

*Life threatening conditions.* Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

* * * * *

*National Institutes of Health (NIH)-approved clinical trial.* An NIH-defined clinical trial, *i.e.,* a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes, in which the NIH collaborates with the study sponsor to provide resources or other support towards the development of the clinical trial and/or analysis of its results. This support may include funding, design, implementation, data analysis, or reporting.

* * * * *

*NIH-sponsored clinical trial.* An NIH-defined clinical trial, *i.e.,* a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes, in which the NIH initiates, funds, manages, and otherwise oversees the clinical trial.

* * * * *

*Severely debilitating conditions.* Diseases or conditions that cause major irreversible morbidity.

* * * * *

■ 3. Amend § 199.4 by:
■ a. Revising paragraph (e)(26)(ii) and (iii);
■ b. Revising paragraph (g)(14); and
■ c. Revising the second paragraph of the note to paragraph (g)(15)(i)(A).

The revisions read as follows:

**§ 199.4 Basic program benefits.**

* * * * *

(e) * * *

(26) * * *

(ii) *Continuous waiver*—(A) *General.* As a result of a demonstration project or rulemaking under which a waiver has been granted in connection with a National Institutes of Health (NIH)-sponsored or approved clinical trial, a determination may be made that it is in the best interest of the government and eligible beneficiaries to provide a waiver for CHAMPUS cost-sharing of routine services and supplies associated with the eligible clinical trial. Only those specified clinical trials identified under this paragraph (e)(26)(ii) and paragraph (e)(26)(iii) of this section have been authorized a continuous waiver under CHAMPUS. Continuous waivers specific to public health emergencies are described in paragraph (e)(26)(iii) of this section.

(B) *National Cancer Institute (NCI) sponsored or approved cancer prevention, screening, and early detection clinical trials.* A continuous waiver under paragraph (e)(26) of this section has been granted for CHAMPUS cost-sharing for those eligible beneficiaries selected to participate in NCI-sponsored or approved Phase I, Phase II, Phase III, and Phase IV studies for the prevention and treatment of cancer.

(*1*) CHAMPUS will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored or approved trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored or approved study. CHAMPUS will cost-share all medical care required as a result of participation in NCI-sponsored or approved studies. This includes purchasing and administering all approved chemotherapy agents (except for NCI-funded investigational drugs provided as part of the clinical trial) and all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

(*i*) The provider seeking treatment for an eligible beneficiary in an NCI approved protocol has obtained pre-authorization for the proposed treatment before initial evaluation;

(*ii*) Such treatments are NCI-sponsored or approved Phase I, Phase II, Phase III, or Phase IV protocols;

(*iii*) The beneficiary continues to meet entry criteria for said protocol; and

(*iv*) The institutional and individual providers are CHAMPUS authorized providers.

(*2*) CHAMPUS will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(*3*) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NCI-sponsored or approved clinical trials.

(*4*) The Director shall issue procedures and guidelines establishing NCI-sponsorship and approval of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NCI-sponsored or approved cancer clinical trials.

(C) *NIH-sponsored and approved clinical trials for severely debilitating diseases, life-threatening diseases, and rare diseases.* The Secretary has approved a continuous waiver under paragraph (e)(26) of this section for CHAMPUS cost-sharing for those eligible beneficiaries selected to participate in NIH-sponsored or approved Phase I, Phase II, Phase III, and Phase IV clinical trials in which the clinical trial studies a new treatment or cure for a specific condition or the treatment of a currently uncontrolled symptom or aspect of that condition, provided that the condition is severely debilitating, life-threatening, or a rare disease.

(*1*) CHAMPUS will cost-share all medical care and testing required to determine eligibility for an NIH-sponsored or approved trial, including

the evaluation for eligibility at the institution conducting the NIH-sponsored or approved study. CHAMPUS will cost-share all medical care (including associated health complications) required as a result of participation in NIH-sponsored or approved studies. This includes purchasing and administering all approved pharmaceutical agents (except for sponsor-funded investigational drugs provided as part of the clinical trial) and all inpatient and outpatient care, including diagnostic, laboratory, rehabilitation, and home health services not otherwise reimbursed under an NIH grant program if the following conditions are met:

(*i*) The provider seeking treatment for an eligible beneficiary in an NIH approved protocol has obtained pre-authorization for the proposed treatment before initial evaluation;

(*ii*) Such treatments are NIH-sponsored or approved Phase I, Phase II, Phase III, or Phase IV protocols;

(*iii*) The beneficiary continues to meet entry criteria for said protocol; and,

(*iv*) The institutional and individual providers are CHAMPUS authorized providers,

(*2*) CHAMPUS will not provide reimbursement for care rendered in the NIH Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(*3*) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NIH-sponsored or approved clinical trials.

(*4*) The Director shall issue procedures and guidelines establishing NIH-sponsorship and approval of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under eligible NIH-sponsored or approved clinical trials.

(iii) *Public health emergency or national emergency waiver*—(A) *General.* A waiver has been granted for CHAMPUS cost-sharing for eligible beneficiaries who participate in Phase I, II, III, or IV trials that are sponsored or approved by the NIH or an NIH Center or Institute for the purposes of treatment or prevention of a Government-recognized epidemic or pandemic that results in a national emergency or public health emergency.

(B) *Infectious disease health emergencies.* CHAMPUS will cover cost-sharing for those eligible beneficiaries selected to participate in NIH-sponsored or approved Phase I, II, III, and IV studies examining the treatment or prevention of an infectious disease (and any associated sequelae) that causes a pandemic or epidemic, when part of a national emergency declared by the President of the United States or a public health emergency declared by the Secretary of Health and Human Services. For eligible beneficiaries receiving covered services overseas, this coverage also includes pandemics and epidemics recognized by foreign governments and pandemics and epidemics recognized by the World Health Organization, although only NIH-approved clinical trials in the region experiencing the Government-recognized pandemic or epidemic qualify for coverage under this provision.

(*1*) CHAMPUS will cost-share all medical care and testing required to determine eligibility for an NIH-sponsored or approved trial, including the evaluation for eligibility at the institution conducting the NIH-sponsored or approved study. CHAMPUS will cost-share all medical care (including associated health complications) required as a result of participation in NIH-sponsored or approved studies. This includes purchasing and administering all approved pharmaceutical agents (except for NIH-funded investigational drugs provided as part of the clinical trial) and all inpatient and outpatient care, including diagnostic, laboratory, rehabilitation, and home health services not otherwise reimbursed under an NIH grant program if the following conditions are met:

(*i*) Such treatments are NIH-sponsored or approved Phase I, Phase II, Phase III, or Phase IV protocols;

(*ii*) The beneficiary continues to meet entry criteria for said protocol; and

(*iii*) The institutional and individual providers are CHAMPUS authorized providers.

(*2*) CHAMPUS will not provide reimbursement for care rendered in the NIH Clinical Center or costs associated with non-treatment research activities associated with the clinical trials.

(*3*) Cost-shares and deductibles applicable to CHAMPUS will also apply under the NIH-sponsored or approved clinical trials.

(*4*) Coverage of cost-sharing for those eligible beneficiaries selected to participate in a clinical trial that meets criteria under paragraph (e)(26)(iii)(B) of this section is effective the date the national or public health emergency is declared and does not terminate at the end of the emergency period.

(*5*) The Director shall issue procedures and guidelines establishing NIH-sponsorship and approval of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under eligible NIH-sponsored or approved clinical trials.

**Note:** A waiver has been authorized for CHAMPUS cost-sharing for those eligible beneficiaries selected to participate in NIH-sponsored or approved Phase I, II, III, and IV studies examining the treatment or prevention of Coronavirus Disease 2019 and its associated sequelae.

* * * * *

(g) * * *

(14) *Study, grant, or research programs.* Services and supplies provided as a part of or under a scientific or medical study, grant, or research program, except as authorized under paragraph (e)(26) of this section.

(15) * * *

(i) * * *

(A) * * *

**Note to paragraph (g)(15)(i)(A):** * * *

Certain cancer drugs, designated as Group C drugs (approved and distributed by the National Cancer Institute), and investigational drugs authorized by the FDA for treatment use under expanded access programs are not covered under TRICARE because they are not approved for marketing by the FDA. However, medical care related to the use of Group C drugs and investigational drugs authorized for treatment use under FDA expanded access programs can be cost-shared under TRICARE when the patient's medical condition warrants their administration, and the care is provided in accordance with generally accepted standards of medical practice.* * *

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Dated: July 24, 2025.

**Aaron T. Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2025–14206 Filed 7–25–25; 8:45 am]

**BILLING CODE 6001–FR–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### 32 CFR Part 310

**[Docket ID: DoD–2024–OS–0049]**

**RIN 0790–AL30**

### Privacy Act of 1974; Implementation

**AGENCY:** Office of the Secretary of Defense (OSD), Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** The Department of Defense (Department or DoD) is issuing a final rule to amend its regulations to exempt portions of DoD–0020, Military Human