Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this IFR.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action does not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This rule does not result in: An annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this IFR to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.12 by:
■ a. Redesignating paragraph (c)(18) through (c)(29) as (c)(19) through (c)(30);
■ b. Adding new paragraph (c)(18).

The addition to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) * * *

(18) Oliceridine (*N*-[(3-methoxythiophen-2-yl)methyl] ({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate) 9245

* * * * *

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–22762 Filed 10–29–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2020–HA–0050]

RIN 0720–AB83

TRICARE Coverage of National Institute of Allergy and Infectious Disease Coronavirus Disease 2019 Clinical Trials

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

ACTION: Interim final rule with request for comments.

SUMMARY: The Assistant Secretary of Defense for Health Affairs (ASD(HA)) issues this interim final rule (IFR) with request for comments to temporarily modify the TRICARE regulation by adding coverage for National Institute of Allergy and Infectious Disease (NIAID)-sponsored clinical trials for the treatment or prevention of coronavirus disease 2019 (COVID–19).

DATES: *Effective date:* This interim final rule is effective on October 30, 2020 through the end of the President's national emergency regarding COVID–19 (Proclamation 9994, 85 FR 15337 (Mar. 18, 2020)). The ASD(HA) will publish a document announcing the expiration date.

Comment date: Comments are invited and must be submitted on or before November 30, 2020.

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

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

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

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

SUPPLEMENTARY INFORMATION: *Expiration Date:* Unless extended after consideration of submitted comments, this IFR will cease to be in effect upon termination of the President's declared national emergency regarding COVID–19, in accordance with applicable law (50 U.S.C.1622(a)).

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

I. Executive Summary

A. Purpose of the Rule

A novel coronavirus (SARS-CoV–2), which causes COVID–19, was first detected in December 2019 and has spread rapidly throughout the world. On March 13, 2020, the President declared a national emergency due to the COVID–19 outbreak, retroactive to March 1, 2020 (Proclamation 9994, 85 FR 15337). According to data from the Centers for Disease Control and Prevention (CDC), on August 24, 2020, there were 5,682,491 confirmed COVID–19 cases in the United States (176,223 confirmed deaths), with the number of cases rapidly expanding each day.[1] Medical experts from NIAID anticipated more cases in the United States and overseas beginning in February 2020.[2]

While stay-at-home orders and recommendations for social distancing have slowed the spread of COVID–19, there is currently no cure for COVID–19, nor are there vaccines capable of preventing transmission of the virus. Many potential COVID–19 treatments and vaccines are being tested in clinical trial settings designed to evaluate their safety and effectiveness. As of June 23, 2020, there were 27 clinical trials underway sponsored by NIAID.

A TRICARE COVID–19-related IFR published on May 12, 2020 (85 FR 27921), provided a temporary exception to the regulatory exclusion prohibiting audio-only telehealth services, temporarily eliminated copayments and cost-shares for TRICARE Prime and Select beneficiaries utilizing authorized telehealth services provided by network providers as a necessary incentive to prevent further spread of COVID–19, and temporarily authorized reimbursement of interstate practice by providers (both in-person and remotely) for care provided to TRICARE beneficiaries when such practice is permitted by federal or state law, even if the provider is not licensed in the state where practicing. That IFR was focused on temporary changes to the TRICARE program to aid in slowing community transmission of COVID–19. A second IFR, published on September 3, 2020 (85 FR 54914–54924), continued efforts by the ASD(HA) to implement temporary regulation changes in response to COVID–19 by focusing on temporary benefit and reimbursement changes that would support treatment of TRICARE beneficiaries. It also implemented two permanent regulation changes consistent with the statutory requirement that TRICARE reimburse like Medicare, to the extent practicable. This third COVID–19-related IFR builds on the efforts of the second IFR to provide beneficiaries access to emerging treatments (including vaccines) for COVID–19 by adding coverage for NIAID-sponsored COVID–19 clinical trials. This regulation implements an agreement entered into by the DoD with the National Institutes of Health (NIH) to cover such clinical trials, in accordance with statutory requirements.

Pursuant to the President's national emergency declaration regarding COVID–19 and as a result of the worldwide COVID–19 pandemic, the ASD(HA) hereby temporarily modifies the regulation to permit coverage of NIAID-sponsored COVID–19 phase I, II, III, and IV clinical trials. Details as follows:

a. 32 CFR 199.4(e)(26): Title 10, U.S.C. 1079(a)(12) authorizes, pursuant to an agreement with the Secretary of Health and Human Services (HHS) and under such regulations as the Secretary of Defense may prescribe, a waiver of the requirement that covered care be medically or psychologically necessary in connection with clinical trials sponsored by the NIH, provided the Secretary of Defense determines that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. On September 19, 2020, the DoD entered into an agreement with NIH to permit coverage of such trials.

Based on an agreement with the National Cancer Institute (NCI) and 32 CFR 199.4(e)(26), TRICARE currently covers NCI sponsored clinical trials related to cancer prevention, screening, and early detection. The intent of these statutory and regulatory provisions is to expand TRICARE beneficiary access to new treatments and to contribute to the development of such treatments.

This IFR will, pursuant to the agreement with the NIH, temporarily amend the regulation to authorize coverage of cost-sharing for medical care and testing of TRICARE-eligible patients who participate in Phase I, II, III, or IV clinical trials examining the treatment or prevention of COVID–19 that are sponsored by NIAID, enforcing the provisions within the agreement between DoD and NIH. Additionally, this change establishes requirements for TRICARE cost-sharing care related to NIAID-sponsored COVID–19 clinical trials; these new requirements mirror the existing requirements set forth in 32 CFR 199.4(e)(26)(ii)(B) for coverage of cancer clinical trials. This change supports statutory intent by encouraging participation of TRICARE beneficiaries in clinical trials studying the prevention or treatment of COVID–19 and contributing to the development of treatments, including vaccines, for COVID–19. This temporary modification will be effective for the duration of the President's national emergency regarding COVID–19; however, a patient who has been enrolled in an NIAID-sponsored clinical trial during the national emergency will continue to have his or her care cost-shared for the duration of that clinical trial, even if the national emergency has ended. Although this temporary provision is only effective for clinical trials for the treatment or prevention of COVID–19, and only for the duration of the national emergency, the DoD may consider expanding coverage to include other NIH clinical trials for the treatment of other diseases after evaluation of associated costs, benefits, risks, and other considerations; any such change would occur through future rulemaking. We invite comment on all benefit changes in this provision of the IFR, including comments on potential expansion of TRICARE's clinical trial benefit beyond cancer clinical trials and COVID–19 clinical trials.

b. Dates. This modification will become effective on October 30, 2020, and will cease to be in effect upon termination of the President's declared national emergency regarding COVID–19.

If the DoD determines it would be appropriate to continue coverage of COVID–19 clinical trials sponsored by NIAID or otherwise expand the clinical trial benefit beyond the duration of the national emergency, the DoD will issue a final rule to make permanent changes.

B. Interim Final Rule Justification

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

[1] COVID–19 case information updated daily on the CDC website at *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.*

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

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

As noted in this preamble, the United States, as well as numerous other countries, has taken unprecedented measures to try to contain or slow the spread of COVID–19. Although studies of potential treatments of COVID–19 are in progress, these studies are expected to take time. Unfortunately, TRICARE beneficiaries who have contracted COVID–19 may not have time to wait for these treatments, given the rapidity with which the disease overtakes individuals who develop the most severe responses to the illness.

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

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

C. Summary of Major Provisions

This provision, 32 CFR 199.4(e)(26), temporarily waives the medical necessity requirements under 10 U.S.C. 1079(a)(12), as authorized by that statute, and establishes a clinical trial benefit for patients participating in NIAID-sponsored clinical trials for the prevention or treatment of COVID–19 during the President's national emergency regarding the COVID–19 outbreak. This provision also removes the reference to the NCI from the 32 CFR 199.4(e)(26) introductory text and authorizes coverage of clinical trials sponsored by any NIH Institute or Center, provided that the statutory requirements are also met (*i.e.,* the creation of an agreement with the Secretary of HHS and the creation of regulatory requirements implementing the agreement). This allows TRICARE coverage of clinical trials sponsored by the NIAID, one of the NIH Institutes and Centers responsible for sponsoring and approving clinical trials related to the treatment and prevention of COVID–19, among other diseases. In other words, this change temporarily removes the restriction that clinical trials under this paragraph be limited to NCI clinical trials.

The current regulatory language only includes waivers for NCI trials related to past or existing demonstrations, and it would be infeasible to create and implement a new COVID–19 demonstration due to the rapid spread of the pandemic, so this provision adds a third category of waiver for public health emergencies and specifically authorizes TRICARE coverage of beneficiary costs related to participation in NIAID-sponsored clinical trials for the treatment or prevention of COVID–19. This third category of waiver for public health emergencies is also a temporary provision; it merely provides an additional waiver type under which the NIAID clinical trials fall and criteria for that waiver type. This provision also establishes regulatory requirements for the coverage of NIAID-sponsored COVID–19 clinical trials to implement the agreement between DHA and NIH, as required by statute.

The DoD and NCI established a partnership in 1994 that allowed TRICARE beneficiaries to participate in cancer clinical trials for certain breast cancer treatments under a demonstration. The demonstration project expanded in 1996 to include all cancers and NCI-sponsored phase II and III cancer treatment clinical trials. The demonstration project partnership was ended by 71 FR 35390, which instead provided a continuous waiver of the medical necessity provision under 10 U.S.C. 1079(a)(12) when care was provided under NIH sponsored trials. That rule established the existing regulations under § 199.4(e)(26) for phase II and III cancer clinical trials. The DoD noted in the preamble for that rule that the demonstration had improved beneficiary access and resulted in contributions to the development of such treatments, justifying the formalization of the clinical trial benefit under TRICARE regulation. The regulation was modified again in 2011, with the addition of coverage for phase I cancer clinical trials (76 FR 2253).

Based on the success of the cancer clinical trial benefit and the urgent need for patients to have access to new treatments during the COVID–19 global pandemic, the ASD(HA) is temporarily waiving the medical necessity provision at 10 U.S.C. 1079(a)(12) for NIAID-sponsored clinical trials for the prevention or treatment of COVID–19 under a public health emergency waiver, as established in this regulation change, which implements the provisions of the agreement between DHA and NIH. TRICARE will cover cost-sharing for medical care and testing required for determining eligibility and participating in Phase I, Phase II, Phase III, and Phase IV clinical trials that meet the requirements set forth in this change. These requirements will implement the agreement between DHA and NIH and will be similar to the existing requirements for coverage of NCI cancer clinical trials, with the following differences: References to NCI and cancer will be changed to NIAID and COVID–19, respectively; Phase IV clinical trials will also be covered under the benefit; and there will be no prior authorization requirement for COVID–19 clinical trials, as the rapid progression of the disease necessitates a more rapid enrollment of beneficiaries and prior authorization would inhibit this enrollment. TRICARE will continue to deny coverage for care rendered in the NIH or costs associated with non-treatment research activities associated with the clinical trials, as well as for any items or services that are already covered under the investigational protocol, such as the drug and device being studied. For example, if the clinical trial were testing the efficacy of a COVID–19 vaccine, that vaccine would already be covered under the protocol (*i.e.,* neither TRICARE nor the patient would be liable for cost-sharing). Only 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 cost-sharing. This is consistent with the coverage policy which has been used for the cancer clinical trial benefit. Coverage will last for the duration of the President's national emergency regarding the COVID–19 outbreak, or, provided that the clinical trial begins and the beneficiary enrolls in the clinical trial before the termination of the national emergency, until the completion of the clinical trial, whichever occurs later. As required by 10 U.S.C. 1079(a)(12), DHA has entered into an agreement with NIH in order to cost-share eligible clinical trials; these regulatory provisions enforce this agreement.

Covering these trials will encourage participation by TRICARE beneficiaries in eligible clinical trials, contribute to the development of treatments and vaccines for COVID–19, and ensure that covered clinical trials meet similar requirements as those for NCI clinical trials for treatment of cancer. Due to the

rapid progression of the COVID–19 pandemic, the severity of the disease in many individuals, and the absence of any existing treatments or vaccines, participation in clinical trials may also be the safest and most successful method of providing TRICARE beneficiaries with early access to care for prevention or treatment of COVID–19. There are already multiple ongoing NIAID-sponsored COVID–19 trials for treatments and vaccines, and we expect many more to be developed. The requirements in this provision, as well as NIAID protocols and institutional review board requirements, will protect participant safety.

Any NIAID-sponsored Phase I, II, III, or IV trial with the purpose of: (1) Preventing infection with COVID–19; (2) diagnosing infection (current or past infection); (3) treating the infection; (4) treating the symptoms of infection (to include associated symptoms such as neurological impairment, cardiovascular illness, or other symptoms as they arise, both acute and long-term); or (5) alleviating pain or other conditions associated with the infection; may be covered under this regulatory provision. Trials that are solely for the purpose of public health research and which do not affect the medical management of the individual patient, such as randomized serological testing to determine prevalence or lasting immunity, may be covered only to the extent that the health plans of other, non-DoD participants are also billed for such care, consistent with TRICARE's regulation at 32 CFR 199.9 regarding appropriate billing practices. Further, care reimbursed under this regulatory provision applies to NIH extramural care, such as NIAID-sponsored trials occurring at partner universities. Care provided at NIH facilities (termed ''intramural'' care) is excluded.

This temporary provision, including the creation of a public health emergency waiver category, is only effective for the period beginning the date this rule publishes in the **Federal Register** through the end of President's national emergency regarding the COVID–19 outbreak. However, we may consider creating additional waivers to cover NIH-sponsored clinical trials in the future, including establishing permanent coverage of NIAID trials, if appropriate, after a review of the costs, benefits, risks, and other considerations. Such waivers would fall under the agreement between DHA and NIH that is being implemented in this provision and would require further rulemaking. We invite public comment on the NIAID COVID–19 clinical trial benefit as implemented in this IFR, as well as the potential expansion of the clinical trial benefit as part of a final rule to cover other NIH Institutes or Centers trials or clinical trials for other diseases.

D. Legal Authority for This Program

This rule is issued under 10 U.S.C. 1073(a)(2) giving authority and responsibility to the Secretary of Defense to administer the TRICARE program.

II. Regulatory History

Title 32 CFR 199.4 is revised every few years to ensure requirements continue to align with the evolving health care field. It was most recently permanently updated on September 29, 2017, with an IFR (82 FR 45438) that implemented the Congressionally-mandated TRICARE Select benefit plan. This revision to 32 CFR 199.4 included the addition of medically necessary foods as a benefit under the TRICARE Basic Program. Paragraph 199.4(e)(26) was last revised on January 13, 2011 (76 FR 2253), with the addition of coverage for NCI sponsored phase I clinical trials.

III. Regulatory Analysis

A. Regulatory Planning and Review

a. Executive Orders

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

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

Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs''

Executive Order 13771 requires that for every significant regulation promulgated, an agency must identify two for elimination and offset its costs. Executive Order 13771 seeks to control costs associated with the government imposition of private expenditures required to comply with Federal regulations and to reduce regulations that impose such costs. Consistent with the analysis of transfer payments under OMB Circular A–4, this interim final rule does not involve regulatory costs subject to Executive Order 13771.

b. Summary

The modifications to paragraph 199.4(e)(26) in this IFR will temporarily permit TRICARE coverage of cost-sharing for NIAID-sponsored clinical trials for the treatment or prevention of COVID–19 for the duration of the President's national emergency for the COVID–19 outbreak. The modifications will also implement the agreement between NIH and DHA by establishing requirements for coverage of Phase I, II, III, and IV clinical trials. TRICARE will cover cost-sharing for medical care and testing required for determining eligibility and participating in clinical trials that meet these requirements.

c. Affected Population

This change affects all TRICARE beneficiaries who wish to participate in NIAID-sponsored clinical trials for the treatment or prevention of COVID–19. TRICARE-authorized providers will be affected by being able to treat TRICARE beneficiaries in NIAID clinical trials. The participation of TRICARE beneficiaries in NIAID-sponsored trials positively affects the general public through the development of treatments and vaccines, although it may negatively affect some individuals who desire to participate in such trials but are unable to do so because they were displaced from participation by TRICARE beneficiaries. TRICARE's health care contractors will be affected by being required to implement the provisions of this regulatory change. State, local, and tribal governments will not be affected.

d. Costs

We estimate the total cost for TRICARE participation in NIAID-sponsored COVID–19 clinical trials will be $3.2M for the duration of the national emergency, with an additional $4.0M for continued care for beneficiaries enrolled in clinical trials prior to termination of the national emergency. There were several assumptions we made in developing this estimate. The duration of the COVID–19 national emergency is uncertain; however, for the purposes of this estimate, we assumed the national emergency would

expire on September 30, 2021 the end of fiscal year (FY) 2021, for ease of calculations. As of the drafting of this IFR, there were 27 NIAID-sponsored COVID–19 clinical trials begun since the start of the national emergency. We assumed 6.5 new trials every 30 days, for a total of 126 trials by September 2021, and that trials would last 17 months, on average, which is the average of the 27 NIAID-sponsored COVID–19 trials used in calculating this estimate. We assumed, based on average trial enrollment (1,770 participants per trial, on average) and that TRICARE beneficiaries would participate in trials at the same rate as the general population, that 4,549 TRICARE beneficiaries would participate through September 2021. Additionally, we assumed that costs for NIAID-sponsored trials will be similar to costs for NCI-sponsored trials, excluding chemotherapy, radiation, and surgery costs; the average government cost for NCI-sponsored trials less the excluded items was $93.00 per participant, per month in FY 2018 and FY 2019. Each of the assumptions in this estimate is highly uncertain, and our estimate could be higher or lower depending on real world events (more or fewer trials, a longer or shorter national emergency, and/or higher or lower participation in clinical trials by TRICARE beneficiaries).

e. Benefits

This change expands the therapies available to TRICARE beneficiaries in settings that ensure informed consent of the beneficiary, and where the benefits of treatment outweigh the potential risks. Participation in clinical trials may provide beneficiaries with benefits such as reduced hospitalizations and/or use of a mechanical ventilator. Although we cannot estimate the value of this avoidance quantitatively, the potential long-term consequences of serious COVID–19 illness, including permanent cardiac or lung damage, are not insignificant. Beneficiary access to emerging therapies that reduce these long-term consequences or even death can be considered to be high-value for those able to participate.

Providers will be positively affected by being able to provide their patients with a broader range of treatment options. The general public will benefit from an increased pool of available participants for the development of treatments and vaccines for COVID–19, as well as the evidence (favorable or otherwise) that results from this participation.

f. Alternatives

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

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

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

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

C. Congressional Review Act

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

D. Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act of 1995''

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 by State, local, and tribal governments, in the aggregate, or by the private sector, in any one year of $100 million in 1995 dollars, updated annually for inflation. This IFR will not impose any Federal mandate for State, local, or tribal governments, nor will it affect private sector costs.

E. Public Law 96–511, ''Paperwork Reduction Act of 1995'' (44 U.S.C. Chapter 35)

32 CFR part 199 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

F. Executive Order 13132, ''Federalism''

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

List of Subjects in 32 CFR Part 199

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

Accordingly, 32 CFR part 199 is amended to read as follows:

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

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

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

■ 2. Amend § 199.4 by:
■ a. Revising the second sentence in paragraph (e)(26).
■ b. Adding new paragraph (e)(26)(iii).
The additions read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(26) * * * By law, and pursuant to an agreement between the Department of Defense and the Department of Health and Human Services, the general prohibition against CHAMPUS cost-sharing of unproven drugs, devices, and medical treatments or procedures may be waived by the Secretary of Defense in connection with clinical trials sponsored or approved by the National Institutes of Health (NIH) or an NIH Institute or Center if it is determined that such a waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments. * * *

(iii) *Public Health Emergency Waiver.*

(A) *General.* During public health emergencies (*e.g.,* a national state of emergency declared by the President), TRICARE may cover cost-sharing for TRICARE-eligible patients who participate in Phase I, II, III, or IV trials that are sponsored by the NIH or an NIH Institute for the purposes of treatment or prevention of the pandemic or public health emergency.

(B) *National Institute of Allergy and Infectious Diseases (NIAID)-sponsored*

clinical trials for COVID–19. For the duration of the President's national emergency regarding the COVID–19 outbreak, TRICARE will cover cost-sharing for those TRICARE-eligible patients selected to participate in NIAID-sponsored Phase I, II, III, and IV studies examining the treatment or prevention of COVID–19 and its associated sequelae (*e.g.,* cardiac and pulmonary issues). TRICARE will continue to cover cost-sharing for any eligible beneficiary enrolled in such a study until the conclusion of that study, even if the national emergency ends before the conclusion of the study.

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

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

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

(*iii*) The institutional and individual providers are TRICARE-authorized providers; and

(*iv*) The requirements for Phase I protocols in paragraph (e)(26)(iii)(B)(*2*) of this section are met.

(*2*) Requirements for Phase I protocols are:

(*i*) Standard treatment has been or would be ineffective, does not exist, or there is no superior non-investigational treatment alternative;

(*ii*) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the non-investigational alternative;

(*iii*) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise; and

(*iv*) The referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of paragraphs (e)(26)(iii)(B)(*2*)(*i*) through (*iii*) of this section.

(*3*) TRICARE 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.

(*4*) Cost-shares and deductibles applicable to TRICARE will also apply under the NIAID-sponsored clinical trials.

(*5*) The Director, Defense Health Agency (or designee), shall issue procedures and guidelines establishing NIAID-sponsorship of clinical trials and the administrative process by which individual patients apply for and receive cost-sharing under NIAID-sponsored COVID–19 clinical trials.

* * * * *

Dated: October 27, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–24114 Filed 10–28–20; 11:15 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2019–0302, EPA–R05–OAR–2019–0676; FRL–10015–49–Region 5]

Air Plan Approval; Ohio; Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving under the Clean Air Act, a State Implementation Plan (SIP) submittal from the Ohio Environmental Protection Agency (OEPA). This SIP revision request, submitted on April 5, 2019, and supplemented on November 21, 2019, consists of amendments and additions to the volatile organic compound (VOC) rules in the Ohio Administrative Code (OAC). These changes provide clarity to facilities that are subject to multiple VOC requirements in the SIP, or whose applicable requirements have been moved to other sections within the OAC as a result of a previous revision. The changes also correct errors and provide general administrative cleanup. An alternative monitoring, recordkeeping, and reporting program was added to the requirements for the BP-Husky Refining LLC, Toledo Refinery. In addition, the SIP submittal adds a mechanism for Ohio to approve alternate limitations for site-specific miscellaneous industrial adhesive and sealant facilities and includes alternate site-specific limitations for certain process lines at the Accel Group, Incorporated (Accel) facility in Wadsworth, Ohio. EPA proposed to approve this action on July 22, 2020, and received no adverse comments.

DATES: This final rule is effective on November 30, 2020.

ADDRESSES: EPA has established dockets for this action under Docket ID Nos. EPA–R05–OAR–2019–0302 (pertaining to amendments to OAC Chapter 3745–21) and EPA–R05–OAR–2019–0676 (pertaining to site-specific alternate VOC SIP limits for the Accel facility). All documents in the dockets are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *www.regulations.gov* or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you telephone Anthony Maietta, Environmental Protection Specialist, at (312) 353–8777 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Anthony Maietta, Environmental Protection Specialist, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8777, *maietta.anthony@epa.gov.*

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

I. Background Information

On July 22, 2020, EPA proposed to approve amendments and additions to the VOC rules located at OAC Chapter 3745–21, including an alternative monitoring, recordkeeping, and reporting program for the BP-Husky Refining LLC, Toledo Refinery at OAC 3745–21–09(T)(4), and alternate site-specific limitations for the Accel facility contained in its September 19, 2019, operating permit (85 FR 44255). An explanation of the applicable Clean Air Act requirements, a detailed analysis of the revisions, and EPA's reasons for