

DEPARTMENT OF DEFENSE**Office of the Secretary****32 CFR Part 199**

[DOD-2018-HA-0062]

RIN 0720-AB75

TRICARE Pharmacy Benefits Program Reforms**AGENCY:** Office of the Secretary, Department of Defense (DoD).**ACTION:** Final rule.

SUMMARY: This rule finalizes Department of Defense (DoD) implementation of Section 702 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18). The law made significant changes to the TRICARE Pharmacy Benefits Program; specifically it: Updated co-payment requirements; authorized a new process for encouraging use of pharmaceutical agents that provide the best clinical effectiveness by excluding coverage for particular pharmaceutical agents that provide very little or no clinical effectiveness relative to similar agents and for giving preferential status to agents that provide enhanced clinical effectiveness; and authorized special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. This rule finalizes the changes made to the TRICARE Pharmacy Benefit Program as stated in the interim final rule.

DATES: This final rule is effective July 6, 2020.

FOR FURTHER INFORMATION CONTACT: Col Markus Gmehlin, Acting, Chief, Pharmacy Operations, Defense Health Agency (DHA), telephone (703) 681-2890.

SUPPLEMENTARY INFORMATION:**I. Executive Summary***A. Public Comments and Responses*

On December 11, 2018 (83 FR 63574-63578), the Department of Defense published an interim final rule titled "TRICARE Pharmacy Benefits Program Reforms" for a 60-day public comment period. The public comment period ended on February 11, 2019. Eight public comments were received. Two of the comments were written by students enrolled in college classes with an assignment involving commenting on **Federal Register** notices. Neither comment was relative to the rule. Two

more comments received were not pertinent to this rule. This section responds to the remaining four public comments.

One comment was a general statement from an individual who admitted not knowing what TRICARE does and to not reading the entire rule but commended the Department for attempting to take care of its beneficiaries. The individual added that Congress and its agencies write laws that are too complicated. This final rule has been carefully reviewed to ensure it is as clear as possible to those affected by it and no changes have been made in that regard.

The remaining three comments represent the pharmaceutical industry, a biotechnology trade association, and an organization focused on patient-centeredness in healthcare. All three comments voiced concerns centering on accessibility of medicines, ensuring a robust process of evaluation of agents when being considered from a clinical benefit, incorporating patient-oriented outcomes that matter, and excluding newly approved drugs. In addition, all three commented on the portion of the rule pertaining to changes in the physician add-on payment rates for medications administered as part of a medical procedure or office visit. We appreciate these comments, which are summarized here, along with DoD's response.

The Department of Defense Pharmacy and Therapeutics (P&T) Committee will be engaging the authority granted by this rule to exclude agents in a judicious manner. Prior to this rule, the DoD was required to include all Food and Drug Administration-approved prescription medications on the DoD Uniform Formulary regardless of safety, effectiveness, or cost. This practice is divergent with current formulary management approaches as applied throughout the healthcare industry and is inconsistent with commercial practice standards. Not only is this practice counter to providing patients with the most clinically effective and safest treatment modalities, but also is imprudent use of tax payer money. The P&T Committee process for evaluating drugs for formulary status is outlined in 32 CFR 199.21(e)(1)(ii) and (iii) which describes the type of materials that may be included as part of the clinical effectiveness and safety conclusions for the drug. This robust process will continue to be the process for evaluating agents being considered for exclusion. In addition to clinical and safety data, patient-oriented outcome data relevant to the drugs being considered is a factor included in the evaluation process. The committee will be guided by specific

criteria that will be used in identifying agents and selecting agents for consideration for exclusion from the benefit. These criteria will include but not be limited to ensuring the availability of alternative agents when an agent is excluded, considering agents for exclusion when safety concerns may outweigh the benefit of the drug, and when the drug is a formulation that includes a combination of drugs that are otherwise excluded. Further, in implementing this rule the committee will not only evaluate drugs for exclusion from coverage but will also include identifying branded drugs that may be moved to Tier 1 status with a lower copayment for beneficiaries. The intent of identifying agents in this manner as well as the new exclusion authority is to yield improved health, smarter spending and better patient outcomes.

As with all P&T recommendations, the Beneficiary Advisory Panel will be able to comment prior to the DHA Director making the final decision. Further, all decisions regarding the DoD Uniform Formulary are routinely monitored and updated to reflect changes in data, updated prescribing criteria, modifications in clinical usage patterns, and cost changes. Any decisions resulting from implementation of this rule will likewise be monitored and reassessed in line with this well-established DoD P&T practice.

In addition to concerns regarding formulary management, four comments representing the pharmaceutical industry and a biotechnology trade association, voiced overlapping concerns on the portion of the rule pertaining to changes in the physician add-on payment rates for medications administered as part of a medical procedure or office visit and are addressed below.

Both a pharmaceutical organization and a biotechnology trade association disagreed with DoD's assumption that the current approach of reimbursing physician administered drugs the Average Sales Price (ASP) plus a six percent add-on creates an incentive to use more expensive drugs. The commenters stated that physician prescribing habits are not driven by the "cost of drugs" or the "payment-per-drug administration"; their views were supported by a report authored by Xcenda, a consulting firm owned by a drug wholesaler. These comments were made in response to a DoD proposal that a median add-on payment for a certain class or category of drugs might be used for all drugs in the group, rather than the current drug-specific six percent

add-on calculation. We recognize that providers' prescribing decisions depend on various factors, and that not all providers may be incentivized similarly or act based on the cost or profit margin of a particular drug. In some cases, there are not good alternatives or the price does not vary greatly among drugs within a particular category, in which case the potential proposed change to a median add-on amount for the group would not matter. However, published studies do support the idea that such incentives may affect prescribing pattern in some situations. A recently published article in a peer-reviewed journal reviewed 18 studies on the association between reimbursement incentives or changes in reimbursement policy and oncology care delivery and found that most studies reported an association consistent with financial incentives (Mitchell et al., *Association Between Reimbursement Incentives and Physician Practice in Oncology, A Systematic Review*, *JAMA Oncol.* 2019;5(6)). This systematic review found that profitability of systemic anticancer agents may affect physicians' choice of drug. Thus, we believe that financial incentives do affect prescribing patterns in some cases and that DoD's proposal may be appropriate to reduce the use of more expensive drugs within a class of drugs when there are appropriate alternatives.

A second comment raised by the pharmaceutical organization and the biotechnology trade association was that DoD's proposal would create a situation that "incentivizes or requires" the use of products that may not be the most appropriate in that situation and that this would lead to worse health outcomes. One commenter also stated that lowering the add-on payment for some drugs could affect the prescribing patterns of some physicians who would choose not to use certain drugs "based on cost considerations alone." We disagree for three reasons: First, DoD's proposal would allow DoD to modify the add-on to the acquisition cost of the physician administered drug (which is currently six percent of the ASP). Nothing in this proposal would require the use of inappropriate products. Second, if DoD does modify the six percent add-on, it would only be done within classes of drugs recommended by the DoD's Pharmacy and Therapeutics Committee and with approval of the DHA Director, which will ensure that the classes of drugs which have modified add-on payments would be selected carefully. Third, because only the add-on payment, not the underlying payment for the drug

would be modified, we do not believe that this proposal would provide large incentives for the use of particular drugs. Rather, we believe that it would remove the incentive to use drugs that have higher costs for no other reason than the higher add-on payment.

A third comment made by the biotechnology trade association is that modifications to the six percent add-on could limit patient access to necessary care and that this could affect patient outcomes. A particular concern raised by the commenter is that modifying the six percent add-on would exacerbate the current situation in which physicians cannot afford to purchase a drug for administration in their offices at an amount less than ASP plus the six percent add-on. We do not think that access will be adversely affected for two reasons. First, DoD is not eliminating the entire add-on; instead it may modify it so that it is set equal to the median add-on within a drug class. As a result, this approach may actually increase the add-on amounts paid for certain drugs. Second, physicians will decide which drugs are prescribed and in all cases these physicians would be reimbursed the Average Sales Price plus an add-on payment, which will be approximately equal to six percent within any drug class. As a result, DoD does not think that there will be access problems. However, DoD will monitor access carefully for any of the products that receive a modified add-on to ensure that there are not access problems for TRICARE beneficiaries.

A fourth comment made by the pharmaceutical organization stated that DoD was "considering a significant potential change, but leaves important terms and standards vague and unclear." The commenter noted that DoD's changes to reimbursement amounts should be made through rulemaking rather than guidance. We have revised the final rule to specify that the Director should be able to adopt an add-on amount equal to six percent of the median amounts for products within a class of products. As a result, the TRICARE reimbursement amount for products within a class of products would be equal to the average sales price plus six percent of the median average sales price of products in that class.

Public comments received in response to DoD's interim final rule, resulted in a revision to the final rule to specify that the physician reimbursement add-on would be six percent of the median within a product class.

B. Purpose of the Final Rule

This rule finalizes Section 702 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18), which does three things: (1) It updates cost-sharing requirements for outpatient pharmaceutical prescriptions filled by retail pharmacies and the TRICARE mail order pharmacy program. (2) It authorizes a new Uniform Formulary process for encouraging use of pharmaceutical agents in the TRICARE Pharmacy Benefits Program that provide the best clinical effectiveness by excluding coverage for particular pharmaceutical agents that provide very little or no clinical effectiveness relative to similar agents and giving preferential status to agents that provide enhanced clinical effectiveness. (3) It authorizes special reimbursement methods, amounts, and procedures to encourage use of high-value products and discourage use of low-value products with respect to pharmaceutical agents provided as part of medical services from authorized providers. This rule finalizes each of these three statutory changes as implemented by the interim final rule.

C. Legal Authority for the Regulatory Action

This final rule is under the primary authority of 10 U.S.C. 1074g, 1079 and 1086, and Section 702 of NDAA FY18. Specifically, section 702(b)(3) of NDAA FY18 authorizes DoD to "prescribe such changes to the regulations implementing the TRICARE program . . . by prescribing an interim final rule." TRICARE program regulations (32 CFR part 199) are issued under statutory authorities including 10 U.S.C. 1074g (the Pharmacy Benefits Program) and 10 U.S.C. 1079 and 1086 (TRICARE medical benefits). Section 702 of NDAA-18 amends both section 1074g and section 1079 (the section 1079 amendment being automatically applicable to section 1086).

D. Summary of Major Provisions of the Final Rule

This rule finalizes the following major provisions:

1. *Updating Cost-Sharing.* Under the authority of section 1074g(a)(6), as amended by Section 702(a) of NDAA FY18, we amended 32 CFR 199.21(i) to cross reference the statutory changes.

2. *Uniform Formulary Changes.* Based on section 1074g(a)(10), as added by Section 702(b)(1) of NDAA FY 18, we changed the Uniform Formulary process under 32 CFR 199.21(e) by authorizing the exclusion of any pharmaceutical agent that provides very little or no

clinical effectiveness relative to similar agents, and preferential status for pharmaceutical agents that have enhanced clinical effectiveness relative to similar agents.

3. *Pharmaceutical Agents as Part of Medical Services.* Based on 10 U.S.C. 1079(q), as added by Section 702(b)(2) of NDAA FY18, we changed provisions of 32 CFR 199.14 to authorize the adoption of special reimbursement methods, amounts and procedures to encourage the use of high value products and discourage the use of low value products—both relative to similar agents—in connection with pharmaceutical agents provided as part of outpatient medical services covered by TRICARE.

II. Provisions of Final Rule

As a result of one public comment noting that DoD's changes to reimbursement amounts should be made through rulemaking rather than guidance the final rule has been revised to specify that the Director should be able to adopt an add-on amount equal to six percent of the median amounts for products within a class of products. As a result, the TRICARE reimbursement amount for products within a class of products would be equal to the average sales price plus six percent of the median average sales price of products in that class.

III. Regulatory Procedures

Executive Order (E.O.) 13771, "Reducing Regulation and Controlling Regulatory Costs"

E.O. 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 final rule does not involve regulatory costs subject to E.O. 13771. Rather, this final rule affects only health care reimbursement payments under the TRICARE program. Aside from the "housekeeping" change to the regulation to incorporate the updated copayment amounts enacted by Congress, the final rule makes two changes to the program: A new authority under the Uniform Formulary process and revised payment authority for pharmaceutical agents as part of medical services.

Executive Order 12866, "Regulatory Planning and Review," Executive Order 13563, "Improving Regulation and Regulatory Review," and Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs"

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (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. This rule has been designated as a "not significant" regulatory action, and not economically significant, under section 3(f) of Executive Order 12866.

Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under the requirements of these Executive Orders.

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that "for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process." This rule is not subject to the requirements of this Executive order because it is not significant under Executive Order 12866.

Additionally, the economic effect of these changes is limited to government reimbursements to health care providers/suppliers that under Circular A-4 are not considered as costs imposed on the economy. The expected reduction in government payments to pharmaceutical companies is based on some predicted increase in use of higher value medications and a corresponding decrease in the use of lower value medications in drug classes where different drugs have comparable clinical effect. The expected value of this shift in use of some medications—*i.e.*, the quantity of the transfer payments—is \$30 million per year.

An initial analysis identified a sample group of candidate drugs that do not offer additional therapeutic benefit over other formulary items. By comparing the current costs to those of a lower-priced comparator and assuming similar utilization rates, the average cost

avoidance was \$1.5M/drug/year, with a more conservative cost avoidance of \$1M/drug/year. When fully implemented, this new process could average 30 drugs per year at a conservative cost avoidance of \$1M/drug/year.

Congressional Review Act, 5 U.S.C. 804(2)

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).

Public Law 96-354, "Regulatory Flexibility Act" (RFA), (5 U.S.C. 601)

The RFA requires that each Federal agency analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. This final rule is not an economically significant regulatory action, and it will not have a significant impact on a substantial number of small entities. Therefore, this rule is not subject to the requirements of the RFA.

Public Law 104-4, Sec. 202, "Unfunded Mandates Reform Act"

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100M in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$140M. This final rule will not mandate any requirements for state, local, or tribal governments or the private sector.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rulemaking does not contain a "collection of information" requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. chapter 35).

Executive Order 13132, "Federalism"

This final rule has been examined for its impact under E.O. 13132, and it does not contain policies that have federalism implications that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of powers and responsibilities among the various levels of Government. Therefore,

consultation with State and local officials is not required.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel.

Accordingly, the interim final rule amending 32 CFR part 199 which published at 83 FR 63574–63578 on December 11, 2018, is adopted as final with the following changes:

PART 199—[AMENDED]

■ 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 § 199.14 by revising paragraph (j)(1)(xi) to read as follows:

§ 199.14 Provider reimbursement methods.

* * * * *

(j) * * *

(1) * * *

(xi) *Pharmaceutical agents utilized as part of medically necessary medical services.* In general, the TRICARE-determined allowed amount shall be equal to an amount determined to be appropriate, to the extent practicable, in accordance with the same reimbursement rules as apply to payments for similar services under Medicare. Under the authority of 10 U.S.C. 1079(q), in the case of any pharmaceutical agent utilized as part of medically necessary medical services, the Director may adopt special reimbursement methods, amounts, and procedures to encourage the use of high-value products and discourage the use of low-value products, as determined by the Director. For this purpose, the Director may obtain recommendations from the Pharmaceutical and Therapeutics Committee under § 199.21 or other entities as the Director, DHA deems appropriate with respect to the relative value of products in a class of products subject to this paragraph (j)(1)(xi). Among the special reimbursement methods the Director may choose to adopt under this paragraph (j)(1)(xi) is to reimburse the average sales price of a product plus six percent of the median of the average sales prices of products in the product class or category. The Director shall issue guidance regarding the special reimbursement methods adopted and the appropriate reimbursement rates.

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Dated: May 7, 2020.
Aaron T. Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.
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BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0283]

RIN 1625–AA00

Safety Zone; Pier 45 Fire Cleanup and Potential Marine Debris, San Francisco Bay, San Francisco, CA

AGENCY: Coast Guard, DHS.
ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of San Francisco Bay around Pier 45 due to emergency response and associated marine debris as a result of a fire on May 23, 2020. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential hazards created by the presence of marine debris and the inability to mark the debris. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port San Francisco or a designated representative.

DATES: This temporary final rule is effective without actual notice from June 3, 2020 through June 30, 2020. For the purposes of enforcement, actual notice will be used from May 29, 2020 through June 3, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG–2020–0283 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Emily Rowan, U.S. Coast Guard Sector San Francisco; telephone (415) 399–7443, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 COTP Captain of the Port San Francisco
 DHS Department of Homeland Security

§ Section
 U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because it is impracticable. The Coast Guard received notice of the need for this safety zone on May 26, 2020. It is impracticable to go through the full rulemaking process, including providing a reasonable comment period and considering those comments, because the Coast Guard must establish this temporary safety zone by May 29, 2020.

The Coast Guard previously issued a temporary final rule for an emergency safety zone effective from May 23, 2020 until May 29, 2020 (Docket number USCG–2020–0007). The Port of San Francisco has indicated that emergency cleanup and the potential presence of associated marine debris from the fire at Pier 45 will continue beyond May 29, 2020.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to protect personnel, vessels, and the marine environment from potential hazards created by the emergency response and the presence of marine debris.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the emergency response and associated marine debris related to the May 23, 2020 fire and identified then as potentially dangerous, will be a safety concern for anyone within a 150-yard radius around Pier 45, San Francisco, CA. For this reason, this temporary safety zone is needed to protect personnel, vessels, and the marine environment in the navigable