14, 2008), the Consumer Product Safety Commission amends 16 CFR part 1120 to read as follows:

PART 1120—SUBSTANTIAL PRODUCT HAZARD LIST

■ 1. The authority citation for part 1120 continues to read as follows:

Authority: 15 U.S.C. 2064(j).

■ 2. In § 1120.2, add paragraph (e) to read as follows:

§ 1120.2 Definitions.

* * * * *

(e) *Extension cord (also known as a cord set)* means a length of factory-assembled flexible cord with an attachment plug or current tap as a line fitting and with a cord connector as a load fitting. Extension cords are used for extending a branch circuit supply of an electrical outlet to the power-supply cord of a portable appliance, in accordance with the National Electrical Code.® For purposes of this rule, the term applies to extension cords that are equipped with National Electrical Manufacturer Association (''NEMA'') 1–15, 5–15 and 5–20 fittings, and that are intended for indoor use only, or for both indoor and outdoor use. The term ''extension cord'' does not include detachable power supply cords, appliance cords, power strips and taps, and adaptor cords supplied with outdoor tools and yard equipment.

■ 3. In § 1120.3, add paragraph (d) to read as follows:

§ 1120.3 Products deemed to be substantial product hazards.

* * * * *

(d) Extension cords that lack one or more of the following specified characteristics in conformance with requirements in sections 2, 9, 16, 19, 20, 21, 26, 30, 31, 32, 84, and 105 of UL 817 (incorporated by reference, see § 1120.4):

(1) Minimum wire size requirement in sections 2, 20, 21, and 30 of UL 817;

(2) Sufficient strain relief requirement in sections 20, 30, and 84 of UL 817;

(3) Proper polarization requirement in sections 9, 19, 20, 30, 31, and 32 of UL 817;

(4) Proper continuity requirement in sections 16, 20, 30, and 105 of UL 817;

(5) Outlet cover requirement (for indoor 2-wire parallel extension cords with polarized parallel-blade and -slot fittings) in sections 20 and 26 of UL 817; or

(6) Jacketed cord requirement (for outdoor use extension cords) in section 30 of UL 817.

■ 4. In § 1120.4, add paragraph (c)(4) to read as follows:

§ 1120.4 Standards incorporated by reference.

* * * * *

(c) * * *

(4) UL 817, *Standard for Cord Sets and Power-Supply Cords,* 11th Edition, dated March 16, 2001, as revised through February 3, 2014 (''UL 817''), IBR approved for § 1120.3(d).

Dated: July 22, 2015.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2015–18294 Filed 7–24–15; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2012–HA–0049]

RIN 0720–AB57

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/ TRICARE: TRICARE Pharmacy Benefits Program

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

ACTION: Final rule.

SUMMARY: This final rule implements new authority for an over-the-counter (OTC) drug program, makes several administrative changes to the TRICARE Pharmacy Benefits Program regulation in order to conform it to the statute, and clarifies some procedures regarding the operation of the uniform formulary. Specifically, the final rule: Provides implementing regulations for the OTC drug program that has recently been given permanent statutory authority; conforms the pharmacy program regulation to the statute (including recent statutory changes contained in the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015) regarding point-of-service availability of non-formulary drugs and copayments for all categories of drugs; clarifies the process for formulary placement of newly approved drugs; and clarifies several other uniform formulary practices.

DATES: This final rule is effective August 26, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. George E. Jones, Jr., Chief, Pharmacy Operations Division, Defense Health Agency, telephone 703–681–2890.

SUPPLEMENTARY INFORMATION:

A. Executive Summary

1. Purpose of Regulatory Action

The final rule is necessary to incorporate new statutory authority for a permanent OTC program, make several administrative changes to the TRICARE Pharmacy Benefits Program regulation to conform to the statute (10 U.S.C. 1074g), and clarify some procedures regarding the uniform formulary.

Legal authority for this final rule is 10 U.S.C. 1074g.

2. Summary of the Final Rule

a. It establishes the process for identifying select OTC products for coverage under the pharmacy benefit program and the rules for making these products available to eligible DoD beneficiaries under the new authority enacted in section 702 of the National Defense Authorization Act for Fiscal Year 2013 (NDAA–13). In general, approved OTC pharmaceuticals will comply with the mandatory generic policy as stated in 32 CFR 199.21(j)(2) and will be available under terms similar to generic prescription medications, except that the need for a prescription and/or a copay may be waived in some circumstances.

b. It conforms the regulation to the statute regarding the point of service where non-formulary drugs are available. They would be generally available in the mail order program, except that if validated as medically necessary, they would be available from military treatment facility pharmacies and from retail pharmacies (at the formulary copay level) as well.

c. It clarifies the process for formulary placement of newly approved innovator drugs brought to market under a New Drug Application approved by the Food and Drug Administration (FDA), giving the Pharmacy and Therapeutics Committee up to 120 days to recommend tier placement on the uniform formulary. During this period, new drugs would be assigned a classification pending status; they would be available under terms comparable to non-formulary drugs, unless medically necessary, in which case they would be available under terms comparable to formulary drugs.

d. As a ''housekeeping'' change, it conforms the rule to the new statutory specifications for copayment amounts in 10 U.S.C 1074g.

3. Costs and Benefits

The benefits of this final rule are that it will more closely conform the regulation to the statute and facilitate more effective administration of the

TRICARE Pharmacy Benefits Program. The final rule will provide savings to the Department of a low-end estimate of $18.4 million and the high-end estimate of $26 million per year based on OTC program savings and estimated potential savings resulting from being able to offer non-formulary drugs through the most cost-effective venue. Revenue from implementation of copay changes resulting from statutory changes contained in the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015 is a low end estimate of $183.1 million annually and a high end estimate for $198.7 million annually. With respect to these statutory changes, this rule simply makes ''housekeeping'' amendments to conform to the specific statutory requirements. DoD has no administrative discretion on this matter.

B. Background

In 1999, Congress enacted 10 U.S.C. 1074g to, among other things, establish a uniform formulary program to incentivize the use of more cost-effective pharmaceutical agents and points of service. There are four points of service under the Pharmacy Benefits Program—military facility pharmacies, retail network pharmacies, retail non-network pharmacies, and the TRICARE mail order pharmacy program (TMOP)—and three uniform formulary tiers—First Tier for generic drugs, Second Tier for preferred brand name drugs (also referred to as ''formulary drugs''), and Third Tier for non-preferred brand name drugs (also referred to as ''non-formulary drugs''). In addition to establishing procedures for assigning drugs to one of the three tiers, the statute includes several other specifications, including that formulary drugs are generally available in all three points of service. Until very recently, the statute also provided that non-formulary drugs would be available in at least one point of service. TRICARE's regulations implementing this statute, issued in 2004, established or continued prior rules for, among other things: Assigning drugs to a formulary tier based on clinical and cost-effectiveness, and point of service availability for the respective tiers. Although the statute required Third Tier drugs to be available in only one point of service, the regulations made them available in two. Under section 702 of the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015 (NDAA–15), non-formulary drugs are now generally limited to the mail order pharmacy point of service (unless there is a validated medical necessity for the drug).

TRICARE's administration of the Pharmacy Benefits Program has achieved some improvements in cost-effectiveness through the retail refund program, increased utilization of formulary management tools such as step-therapy and prior authorizations, and increased copays. The final rule will provide savings to the Department of a low-end estimate of $18.4 million and the high-end estimate of $26 million per year based on a combination of the savings from the current OTC demonstration program and estimated potential savings resulting from being able to offer non-formulary drugs through the most cost-effective venue. Revenue from implementation of copay changes resulting from statutory changes contained in the Carl Levin and Howard P. ''Buck'' McKeon National Defense Authorization Act for Fiscal Year 2015 is a low end estimate of $183.1 million annually and a high end estimate for $198.7 million annually. As a ''housekeeping'' matter, this rule includes the necessary changes to conform to the new statutory specifications over which DoD has no administrative discretion. However, overall costs of the TRICARE Pharmacy Benefits Program have continued to increase substantially, from approximately $2 billion in fiscal year 2001, to approximately $7 billion for fiscal year 2012. Like other large health plans, DoD is experiencing rising pharmacy costs due to new expensive products, shorter hospital stays, and in some cases higher drug prices. DoD also has an expanded beneficiary population, which now includes ''TRICARE-for-Life'' beneficiaries and some members of the Selected Reserves and their families. Retail prescription co-payments reflect the cost for up to a 30-day supply of the prescription, while mail order co-payments cover up to a 90-day supply. This difference is part of the incentive for beneficiaries to use the more cost-effective mail order program, as is the recent elimination of copayments for mail order generic drugs. Encouraging increased use of DoD's more cost-effective points of service (*i.e.,* the mail order pharmacy or a military treatment facility pharmacy) and more cost-effective pharmaceutical products (*i.e.,* those on First Tier and Second Tier) continues to be a TRICARE program objective.

C. Summary of the Final Rule

This final rule establishes the process for selecting OTC products for coverage under the TRICARE pharmacy benefits program and would provide the guidelines for making selected OTC products available to eligible DoD beneficiaries. The OTC drugs demonstration project began through the TRICARE Mail Order Pharmacy program in May 2007 and in the TRICARE Retail Pharmacy program in October 2007. Due to the brevity of the demonstration, particularly in the retail pharmacy venue, in June 2009 an interim report to Congress was submitted with preliminary cost savings estimates and positive beneficiary feedback. In order to validate the initial results and identify areas for improvement to the program, the Department of Defense (DoD) extended the program through a **Federal Register** notice published on December 16, 2009. The demonstration program was due to terminate November 4, 2012. The DoD extended the OTC demonstration for another 2 years through publishing a **Federal Register** notice, while awaiting permanent legislative authority. A report to Congress in 2012 stated that DoD saved approximately $62M during the course of the OTC demo. Section 702 of NDAA–13 amended subsection (a)(2) of section 1074g of title 10, United States Code, providing permanent authority to place selected over-the-counter drugs on the uniform formulary.

The new legislation authorizes DoD to place selected OTC drugs on the uniform formulary and make such drugs available to eligible covered beneficiaries (eligibility specified in 32 CFR 199.3). The basic criteria regarding selection of OTC products for consideration are cost-effectiveness and patient access. DoD will consider and approve an OTC drug for inclusion in the uniform formulary only if it is expected to reduce government costs relative to a clinically comparable alternative drug that would otherwise be consumed and/or if an OTC product provided access to care not otherwise met by prescription-only products (*e.g.,* Plan B contraceptive). An OTC drug may be included on the uniform formulary only if the Pharmacy and Therapeutics (P&T) Committee finds that the OTC drug is both cost effective and clinically effective. Clinical effectiveness is judged by the criteria found in 32 CFR 199.21(e)(1)(i–ii) while cost effectiveness is determined based on criteria found in 32 CFR 199.21(e)(2). This cost-effectiveness standard is reinforced by the requirement for physician supervision through issuance of a prescription for the OTC drug. This requirement applies unless it is waived based on a recommendation of the Pharmacy and Therapeutics Committee for the use of the drug for certain medical situations, such as emergency care treatment.

The selected OTC drugs would be placed in First Tier with the corresponding copays applicable to the point-of-service involved. Alternatively, based on the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the retail copay may be waived and $0.00 copay established for the particular OTC drug in all points of service. No cost sharing is required at any of the three points of service for a uniformed service member on active duty.

This final rule also makes several administrative changes to the TRICARE Pharmacy Benefits Program regulation to conform more closely to the statute (10 U.S.C. 1074g) and to clarify some procedures regarding the uniform formulary. One change aligns the regulation with the statute regarding the point of service where non-formulary drugs are generally available. Until very recently, the statute required availability in one of the three primary points of service (military facility, retail network, and mail order program). The current regulation specifies that non-formulary (Third Tier) drugs are generally unavailable in military facilities and generally available in the retail network and by mail order. The proposed rule would have revised this to state that non-formulary drugs would generally be available in the retail network or by mail order, but the Pharmacy and Therapeutics Committee could recommend and the DHA Director could approve limiting the drug to only one venue based on determinations that there is no significant clinical need and there is a significant additional government cost for access to both venues. However, since publication of the proposed rule, Congress has amended the statute to specify that non-formulary drugs will only be generally available in the mail order program. This removes any DoD discretion on the matter. Therefore, this final rule states that non-formulary drugs are generally available only in the mail order program. It should be noted that existing statutory and regulatory provisions allowing an exception to this in cases of medical necessity for the non-formulary drug remain in effect. Therefore, when medically necessary, non-formulary drugs are available at military treatment facility pharmacies and also from retail pharmacies. In the latter case, the copay will be the same as is applicable to formulary drugs.

This change will reinforce DoD policy, which encourages use of more cost-effective drugs and points of service. A beneficiary always has the option of asking the health care provider to change the prescription to a comparable formulary drug, or, in cases of medical necessity, obtaining approval for dispensing the non-formulary drug at the formulary copayment amount. Like all other health plans with formularies, physicians make professional decisions regarding formulary alternatives, often in consultation with the pharmacist in light of the individual patient's circumstances. Under DoD's policy, when a physician provides written justification stating why the non-preferred drug is expected to have better clinical outcomes than the preferred drug, the non-formulary drug may be obtained at the formulary copay. This process is clearly explained to the provider by the Pharmacy Benefit manager through telephone or fax when the situation occurs. Another option for most prescriptions when the beneficiary prefers a non-formulary drug is to have the prescription transferred to the mail order program, which has a lower co-payment for a 90-day supply of a non-formulary drug ($46) than the retail point of service would have for three 30-day prescriptions for a formulary drug (3 times $20).

Another administrative change in this final rule clarifies the process for formulary placement of innovator drugs newly approved by the Food and Drug Administration. Current practice for brand name drugs is that they are placed in the Second Tier the day FDA approves the drug. This practice has not led to the most cost-effective placement of these newly approved drugs and has the potential for confusion among patients and physicians if the drug is soon thereafter moved to Third Tier. DoD proposes that newly approved drugs be evaluated for their relative clinical benefit and relative cost, as compared to other drugs in the same class, at the next quarterly meeting of the Pharmacy and Therapeutics (P&T) Committee following FDA approval. A recommendation will then be made to the Director of the Defense Health Agency for tier placement of the drug.

The current statute and regulation do not specifically address the status of the drug from the date of FDA approval to the date the P&T Committee's recommendation is eventually implemented. This final rule addresses this by considering the newly approved drug to be in a classification pending status and covered by TRICARE under terms applicable to Third Tier drugs, and by providing a period of up to 120 days for the P&T Committee to make a final determination with respect to formulary classification. Tier classification will normally occur at the next quarterly meeting following FDA approval, but in cases when the FDA approval happens too close to a scheduled meeting for the necessary research to be done, the drug would be considered at the following meeting. The 120-day time period accommodates this. During the period prior to a decision on tier placement, the newly approved drug will be covered by TRICARE under Third Tier terms.

Under the current rule, new drugs are immediately placed on the Second Tier (formulary brand-name drugs). Once the new drug is properly reviewed and compared to all other drugs in its class, it is often moved to the Third Tier (non-formulary), *i.e.,* no clinical or cost advantage. Under this final rule, very briefly deferring tier placement pending a review would not require a ''tier move'' if the review finds no clinical or cost advantage. Movement of drugs between the tiers is always confusing to beneficiaries even though they are notified in writing of the change. The change to the rule will lessen the likelihood of a tier move for the new product.

This final rule also incorporates into the regulation several details of current practice. While the current regulation provides that a uniform formulary drug that is not a generic drug may be grouped for copayment purposes with generic drugs if it is judged to be as cost effective as generic drugs in the same drug class, this final rule adds that a generic drug may be classified as non-formulary if it is less cost-effective than non-generic formulary drugs in the same drug class. The Uniform Formulary process requires the P&T committee to make recommendations to the Director, Defense Health Agency who approves or disapproves each recommendation after reviewing comments from the Beneficiary Advisory Panel on the recommendations. In the case of all generic drugs, the beneficiary copayment amount for any prescription may not exceed the total charge to TRICARE for that prescription.

Finally, this final rule makes a ''housekeeping'' change to the paragraph on cost sharing amounts to make it conform to the current statutory specifications established by NDAA–13 and NDAA–15. In the current regulation, copays were calculated based on the previous statute that stated that the Third Tier copay could be no more than 20% for active duty dependents or 25% for retirees and their dependents of the cost of the drug. The NDAA–13 legislation provided specific set dollar amounts for copays from January 2014 through January 2023. NDAA–15 adjusted several of these amounts by $3 per prescription and

generally eliminated availability of non-formulary drugs at the retail pharmacy point of service. This has rendered the text of the current regulation out of date and no longer accurate. The new text of the regulation matches the current statutory specifications. The final rule also reissues without change paragraphs (h)(4) and (i)(2)(ii)(D) to clarify agency intent and correct a technical misstatement in a 2011 **Federal Register** publication.

D. Summary of and Response to Public Comments

The proposed rule was published in the **Federal Register** (79 FR 56312) September 19, 2014, for a 60-day comment period. We received three comments on the proposed rule from three commenters. We appreciate these comments, which are summarized here, along with DoD's response.

Comment: One comment expressed concern regarding limiting the availability of non-formulary pharmaceuticals to one point of service based on Pharmacy and Therapeutics Committee recommendations and approval by the Director, Defense Health Agency. The commenter's concern was specific to limiting the availability of compounded medications to one point of service.

Response: This final rule is not addressing compounded medications and the rule is doing nothing more that conforming with the current statutory specification (based on NDAA–15) that non-formulary drugs are generally only available through the mail order point of service. (Existing regulatory provisions at 32 CFR 199.21(h)(3)(iv) stating that with validated medical necessity, non-formulary drugs are provided at formulary drug copays remain in effect.)

Comment: One commenter objected to the proposed rule provision that newly approved drugs will be maintained for a brief administrative review period in a ''classification pending'' status and be available under terms comparable to Third Tier drugs. The commenter expressed the view that this is contrary to the statute, which establishes the default position for brand name drugs at the Second Tier, and could impair prompt access to important new drugs.

Response: DoD believes this change does not conflict with the statute, which does not address the issue of status pending the first opportunity of the Pharmacy and Therapeutics Committee to consider the appropriate tier placement of the drug. TRICARE is trying to minimize the beneficiary confusion associated with tier changes. This administrative review period is very short. It will last not more than 120 days, and often a shorter period. And perhaps most importantly, in any case in which there is a validated medical necessity for the newly approved drug, it will be available on the same terms as apply to Tier Two drugs. Thus, DoD is adopting this brief administrative review period for initial tier placement of newly approved brand name drugs.

Comment: One commenter expressed support for the proposed provisions on over-the-counter drugs, but recommended that a preamble summary of the provision and inclusion of an example of emergency contraception be written into the regulatory text.

Response: DoD acknowledges the commenter's agreement with the policy, but sees no need to revise the regulatory language. It correctly states the intended policy, and providing an example of a particular drug DoD expects to be covered by that policy is more appropriate for a preamble summary than regulatory text.

E. Regulatory Procedures

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

Executive Order (EO) 12866 and 13563 require that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of $100 million or more in any one year. The DoD has examined the economic, legal, and policy implications of this final rule and has concluded that it is not an economically significant regulatory action under Section 3(f)(1) of the EO. The rule has been reviewed by the Office of Management and Budget.

Congressional Review Act, 5 U.S.C. 801, et seq.

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. For this purpose we note that the budget savings identified in this preamble are mostly associated with ''housekeeping'' changes to the Code of Federal Regulations to conform to specific statutory requirements, with respect to which DoD has no administrative discretion.

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

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribunal governments, in aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.

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

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This final rule does not have a significant impact on a substantial number of small entities.

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

This final rule contains no new information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3511).

Executive Order 13132, ''Federalism''

This final rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on the States; the relationship between the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Claims, Health care, Health insurance, Military personnel, Pharmacy Benefits.

Accordingly, 32 CFR part 199 is amended as follows:

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. Section 199.21 is amended by:
■ a. Adding paragraph (b)(3));
■ b. Adding paragraph (g)(5);
■ c. Revising paragraphs (h)(3)(i) and (ii);
■ d. Republishing paragraph (h)(4);
■ e. Adding paragraph (h)(5);
■ f. Revising paragraphs (i)(2)(ii) through (v), and (i)(2)(x); and
■ g. Adding paragraphs (i)(2)(xii) and (j)(4) and (5).

The additions and revisions read as follows:

§ 199.21 TRICARE Pharmacy Benefits Program.

* * * * *

(b) * * *

(3) *Over-the-counter drug.* A drug that is not subject to section 503(b)(1) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

* * * * *

(g) * * *

(5) *Administrative procedure for newly approved drugs.* In the case of a newly approved innovator drug, other than a generic drug, the innovator drug will, not later than 120 days after the date of approval by the Food and Drug Administration, be added to the uniform formulary unless prior to that date the P&T Committee has recommended that the agent be listed as a non-formulary drug. If the Director, DHA subsequently approves that recommendation, the drug will be so listed. If the Director, DHA disapproves the recommendation to list the drug as non-formulary Third Tier, the drug will be then classified per the Director's decision. If, prior to the expiration of 120 days, the P&T Committee recommends that the agent be added to the uniform formulary and the recommendation is approved by the Director, DHA, that will be done as soon as feasible. Pending action under this paragraph (g)(5), the newly approved pharmaceutical agent will be considered to be in a classification pending status and will be available to beneficiaries under Third Tier terms applicable to all other non-formulary agents.

* * * * *

(h) * * *

(3) *Availability of non-formulary pharmaceutical agents.*—(i) *General.* Non-formulary pharmaceutical agents are generally not available in military treatment facilities or in the retail point of service. They are available in the mail order program.

(ii) *Availability of non-formulary pharmaceutical agents at military treatment facilities.* Even when particular non-formulary agents are not generally available at military treatment facilities, they will be made available to eligible covered beneficiaries through the non-formulary special approval process as noted in this paragraph (h)(3)(ii) when there is a valid medical necessity for use of the non-formulary pharmaceutical agent.

* * * * *

(4) *Availability of vaccines/immunizations.* A retail network pharmacy may be an authorized provider under the Pharmacy Benefits Program when functioning within the scope of its state laws to provide authorized vaccines/immunizations to an eligible beneficiary. The Pharmacy Benefits Program will cover the vaccine and its administration by the retail network pharmacy, including administration by pharmacists who meet the applicable requirements of state law to administer the vaccine. A TRICARE authorized vaccine/immunization includes only vaccines/immunizations authorized as preventive care under the basic program benefits of § 199.4 of this part, as well as such care authorized for Prime enrollees under the uniform HMO benefit of § 199.18. For Prime enrollees under the uniform HMO benefit, a referral is not required under paragraph (n)(2) of § 199.18 for preventive care vaccines/immunizations received from a retail network pharmacy that is a TRICARE authorized provider. Any additional policies, instructions, procedures, and guidelines appropriate for implementation of this benefit may be issued by the TMA Director.

(5) *Availability of selected over-the-counter (OTC) drugs under the pharmacy benefits program.* Although the pharmacy benefits program generally covers only prescription drugs, in some cases over-the-counter drugs may be covered and may be placed on the uniform formulary.

(i) An OTC drug may be included on the uniform formulary upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, based on a finding that it is cost-effective and clinically effective, as compared with other drugs in the same therapeutic class of pharmaceutical agents. Clinical need is judged by the criteria found in paragraph (e)(1)(i) and (ii) of this section. Cost effectiveness is determined based on criteria found in paragraph (e)(2) of this section.

(ii) OTC drugs placed on the uniform formulary, in general, will be treated the same as generic drugs on the uniform formulary for purposes of availability in MTF pharmacies, retail pharmacies, and the mail order pharmacy program and other requirements. However, upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the requirement for a prescription may be waived for a particular OTC drug for certain emergency care treatment situations. In addition, a special copayment may be established under paragraph (i)(2)(xii) of this section for OTC drugs specifically used in certain emergency care treatment situations.

(i) * * *

(2) * * *

(ii) For pharmaceutical agents obtained from a retail network pharmacy there is a:

(A) $20.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) $8.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent.

(C) $0.00 co-payment for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

(iii) For formulary and generic pharmaceutical agents obtained from a retail non-network pharmacy there is a 20 percent or $20.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For pharmaceutical agents obtained under the TRICARE mail-order program there is a:

(A) $16.00 co-payment per prescription for up to a 90-day supply of a formulary pharmaceutical agent.

(B) $0.00 co-payment for up to a 90-day supply of a generic pharmaceutical agent.

(C) $46.00 co-payment for up to a 90-day supply of a non-formulary pharmaceutical agent. (D) $ 0.00 co-payment for smoking cessation pharmaceutical agents covered under the smoking cessation program.

* * * * *

(x) The per prescription co-payments established in this paragraph (i)(2) may be adjusted periodically based on experience with the uniform formulary, changes in economic circumstances, and other appropriate factors. Any such adjustment must be approved by the Assistant Secretary of Defense (Health Affairs). These additional requirements apply:

(A) Beginning January 1, 2016, the amounts specified in this paragraph (i)(2) shall be increased annually by the percentage increase in the cost-of-living adjustment by which retired pay is increased under 10 U.S. Code section 1401a for the year, rounded down to the nearest dollar. However, with respect to any amount of increase that is less than $1 or any amount lost in rounding down to the nearest dollar, that amount shall be carried over to, and accumulated with, the amount of the increase for the subsequent year or years and made when the aggregate amount of increases carried over for a year is $1 or more.

(B) Effective January 1, 2023 (unless otherwise provided by law), the Assistant Secretary of Defense for Health Affairs may adjust the amounts specified in this paragraph (i)(2) as considered appropriate. Between January 1, 2016, and January 1, 2023, the only adjustments allowed are the cost of living adjustments described in paragraph (i)(2)(x)(A) of this section, unless otherwise provided by law.

* * * * *

(xii) *Special copayment rule for OTC drugs in the retail pharmacy network.*

As a general rule, OTC drugs placed on the uniform formulary under paragraph (h)(5) of this section will have copayments equal to those for generic drugs on the uniform formulary. However, upon the recommendation of the Pharmacy and Therapeutics Committee and approval of the Director, DHA, the copayment may be established at $0.00 for any particular OTC drug in the retail pharmacy network.

(j) * * *

(4) Upon the recommendation of the Pharmacy and Therapeutics Committee, a generic drug may be classified as non-formulary if it is less cost effective than non-generic formulary drugs in the same drug class.

(5) The beneficiary copayment amount for any generic drug prescription may not exceed the total charge for that prescription.

* * * * *

Dated: July 21, 2015.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–18290 Filed 7–24–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 3, 50, 51, 52, 62, 67, 72, 80, 82, 83, 84, 90, 96, 100, 101, 110, 117, 150, 151, 155, 156, 161, 162, 164, 165, 177, and 183

[Docket No. USCG–2015–0433]

RIN–1625–AC25

Navigation and Navigable Waters; Technical, Organizational, and Conforming Amendments

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule makes non-substantive technical, organizational, and conforming amendments to existing regulations throughout Title 33 of the Code of Federal Regulations. These changes provide the public with more accurate and current regulatory information, but they do not change the impact on the public of any Coast Guard regulation.

DATES: This final rule is effective July 27, 2015.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2015–0433. To view documents mentioned in this preamble, go to *www.regulations.gov,* type the docket number in the ''SEARCH'' box, and click ''Search.'' If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in room W12–140 of the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this final rule, call or email Mr. Paul Crissy, Coast Guard; telephone 202–372–1093, email *Paul.H.Crissy@uscg.mil.* If you have questions on viewing the docket, call Ms. Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Table of Contents for Preamble

I. Abbreviations

CFR—Code of Federal Regulations
DHS—Department of Homeland Security
E.O.—Executive Order
FR—Federal Register
NOAA—National Oceanic and Atmospheric Administration
OMB—Office of Management and Budget
Pub. L.—Public Law
§—Section symbol
U.S.C.—United States Code

II. Regulatory History

This rule is subject to several exceptions from the regulatory procedure requirements of 5 U.S.C. 553. Before issuing this rule, the Coast Guard did not provide a notice of proposed rulemaking, because it is not required to do so because this rule involves rules of agency organization, procedure, or practice.[1] Moreover, notice and comment is unnecessary because the rule does not change the impact on the public of any Coast Guard regulation, but only makes non-substantive organizational and conforming amendments. For that reason, the Coast Guard finds it has good cause to issue this rule without first giving the public an opportunity to comment,[2] and to make the rule effective less than 30 days after publication in the **Federal Register**.[3]

III. Basis and Purpose

The legal basis of this rule is found in 5 U.S.C. 552(a) and 553; 14 U.S.C. 2(3) and 631–633; 33 U.S.C. 471 and 499; and Department of Homeland Security Delegation No. 0170.1.

The purpose of this rule is to provide the public with more accurate and current regulatory information by making technical, organizational, and conforming amendments to existing regulations throughout Title 33 of the Code of Federal Regulations (33 CFR). This rule does not change the impact on the public of any Coast Guard regulation.

IV. Discussion of the Rule

Each year, the Coast Guard issues technical, organizational, and conforming amendments to existing regulations in 33 CFR. These annual ''technical amendments'' provide the public with more accurate and current regulatory information, but do not change the impact on the public of any Coast Guard regulation.

The rule makes changes in the following sections of 33 CFR:

Sections 3.35–1, 3.35–35, 3.40–1(b), 3.40–10: Shift several Seventh and Eighth Coast Guard District boundaries so that they coincide with existing county political boundaries.

Part 50 authority line: Change from ''Sec. 8, 18 Stat. 127, as amended, sec. 302, 58 Stat. 287, as amended; 14 U.S.C. 92, 38 U.S.C. 693i'' to ''Sec. 10 U.S.C. 1554; 14 U.S.C. 92, 633; Department of Homeland Security Delegations No. 0160.1(II)(B)(1), 0170.1(II)(23)'' to conform to obsolete statutory references to current equivalents. Specifically, 18 Stat. 127 was superseded by 14 U.S.C. 92 and 633 in 1949. Section 302 of 58 Stat. 287 was codified at 38 U.S.C. 693i; that section was later re-enacted as 10 U.S.C. 1553 and 1554 in Public Law 85–857 in 1958.

Sections 50.1, 50.3, 50.5, 50.6: Change ''officer'' to ''member or former member'' to reflect change to 10 U.S.C. 1554 authorization for Retiring Review Board.

Part 51 authority line: Change from ''10 U.S.C. 1553; Pub. L. 107–296, 116 Stat. 2135'' to ''10 U.S.C. 1553; 14

[1] 5 U.S.C. 553(b)(A).

[2] 5 U.S.C. 553(b)(B).

[3] 5 U.S.C. 553(d)(3).