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DEPARTMENT OF DEFENSE

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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: Proposed rule.

SUMMARY: This proposed rule would implement new authority authorizing an over-the-counter (OTC) drug program, make several administrative changes to the TRICARE Pharmacy Benefits Program regulation in order to conform it more closely to the statute, and clarify some procedures regarding the operation of the uniform formulary. Specifically, the proposed rule would: provide implementing regulations for the OTC drug program that has recently been given permanent statutory authority; conform the pharmacy program regulation to the statute regarding point-of-service availability of non-formulary drugs and copayments for all categories of drugs; clarify the process for formulary placement of newly approved drugs; and clarify several other uniform formulary practices.

DATES: Written comments received at the address indicated below by [insert 60 days after date of publication in the Federal Register] will be considered and addressed in the final rule.

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

Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the instructions for submitting comments.

Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (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: Dr. George E. Jones, Jr., Chief, Pharmacy Operations Division, Defense Health Agency, telephone 703-681-2890.

SUPPLEMENTARY INFORMATION:

A. EXECUTIVE SUMMARY.

1. Purpose of the Proposed Rule.

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

The legal authority for this proposed rule is 10 U.S.C. 1074g.

2. Summary of the Major Provisions of the Proposed Rule.

a. It would establish 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 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 would conform the regulation to the statute regarding the number of points of service where non-formulary drugs are required to be available. They would be generally available in the retail program and the mail order program unless the Pharmacy and Therapeutics Committee recommends limiting the drug to a single point of service – retail or mail order – based on determinations that there is no significant clinical need and there is a significant additional government cost for access in both, and the recommendation is approved by the Director, Defense Health Agency (DHA).

c. It would clarify 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 in retail and mail order under terms comparable to non-formulary drugs.

d. As a “housekeeping” change, it would conform the rule to the new statutory specifications for copayment amounts under section 712 of NDAA-13.

3. Costs and Benefits.

The benefits of the proposed 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 proposed 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.

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, such as: that formulary drugs are generally available in all three points of service; and that non-formulary drugs are 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.

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 proposed 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. 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. PROVISIONS OF THE PROPOSED RULE.

The proposed rule would establish the process for selecting OTC products for coverage under the TRICARE pharmacy benefit 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 is cost-effectiveness and patient access. DoD will consider and approve an OTC drug for inclusion under this proposal 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 C.F.R. 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 (i.e., \$0.00 in military facilities and mail order, \$5.00 in the retail network). Alternatively, based on the recommendation of the Pharmacy and Therapeutics

Committee and approval of the Director, DHA, the retail copay may be waived and a \$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.

Another purpose of this proposed rule is to make 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 is to align the regulation with the statute regarding the number of points of service where non-formulary drugs are required to be available. The statute requires 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, by contrast, states that non-formulary drugs are generally required to be available in the retail program and the mail order program. This requirement applies unless the Pharmacy and Therapeutics Committee recommends 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 at all venues, and the recommendation is approved by the Director, Defense Health Agency (DHA).

In this context, clinical need means there are reasons in the course of clinical care that the non-formulary drug is required over other, preferred, formulary drugs. A finding of clinical need also means that limiting access to one point of service would affect the ability to deliver prompt, appropriate medical care, for example timing of therapy or use of the drug for acute care indications, among other concerns. This change would 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 lower co-payments for non-formulary drugs than the retail point of service.

Another administrative change would clarify 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 TRICARE Management Activity for tier placement of the drug.

The current regulation does 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.

The proposed rule would address 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 the proposed 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 proposed change to the rule will lessen the likelihood of a tier move for the new product.

The proposed rule would also incorporate 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, the proposed rule would add 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, the proposed rule would make a “housekeeping” change to the paragraph on cost sharing amounts to make it conform to the current statutory specifications established by NDAA-13. 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. This has rendered the text of the current regulation out of date and no longer accurate. The new proposed text of the regulation matches the current statutory specifications. The proposed 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. 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 proposed rule and has concluded that it is not an economically significant regulatory action under Section 3(f)(1) of the EO. The

rule is a significant regulatory action and it 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.

This proposed rule is not a major rule under the Congressional Review Act.

Sec. 202, Pub. L. 104-4, “Unfunded Mandates Reform Act”

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal 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 proposed 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 proposed 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 proposed 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.

Public Comments Invited

This is a proposed rule. DoD invites public comments on all of its provisions.

List of Subjects in 32 CFR Part 199

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

Accordingly, 32 CFR part 199 is proposed to be 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 new paragraphs (b)(3) and (g)(5), (h)(5), (i)(2)(xii) and (j)(4) and (5),
- b. Revising paragraphs (h)(3)(i) and (ii), (i)(2)(ii) through (v), and (i)(2)(x), and
- c. Republishing paragraph (h)(4) without change.

The additions and revisions read as follows:

§ 199.21. 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 (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. They are generally available in the retail program and the mail order program unless the Pharmacy and Therapeutics Committee recommends limiting a particular non-formulary drug to only one of these points of service based on determinations that there is no significant clinical need and there is a significant additional government cost for access in both, and the recommendation is approved by the Director, DHA. Clinical need is judged by the criteria found in paragraph (e)(1)(i-ii) of this section. Cost effectiveness is determined based on criteria found in paragraph (e)(2) of this section.

(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 paragraph (h)(3)(ii) of this section 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-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) * * *

(i) * * *

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

(A) \$ 17.00 co-payment per prescription required for up to a 30-day supply of a formulary pharmaceutical agent.

(B) \$ 5.00 co-payment per prescription for up to a 30-day supply of a generic pharmaceutical agent.

(C) \$ 44.00 co-payment per prescription for up to a 30-day supply of a non-formulary

pharmaceutical agent.

(D) \$ 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 \$ 17.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

(iv) For non-formulary pharmaceutical agents obtained at a retail non-network pharmacy there is a 20 percent or \$ 44.00 co-payment (whichever is greater) per prescription for up to a 30-day supply of the pharmaceutical agent.

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

(A) \$ 13.00 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) \$ 43.00 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) of this section 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, 2014, the amounts specified in this paragraph (i)(2) of this section 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) of this section as considered appropriate. Between January 1, 2014, 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.

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Dated: September 15, 2014.

Aaron Siegel,
Alternate OSD Federal Register Liaison Officer,
Department of Defense.

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