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DEPARTMENT OF DEFENSE

Office of the Secretary

[DoD-2009-HA-0151; 0720-AB37]

32 CFR Part 199

Civilian Health and Medical Program of the Uniformed Services
(CHAMPUS)/TRICARE: Inclusion of Retail Network Pharmacies as Authorized
TRICARE Providers for the Administration of TRICARE Covered Vaccines

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

ACTION: Interim final rule.

SUMMARY: This interim final rule allows a TRICARE retail network pharmacy to be an authorized provider for the administration of three TRICARE-covered vaccines in the retail pharmacy setting. The three immunizations are H1N1 vaccine, seasonal influenza vaccine, and pneumococcal vaccine. In addition, this interim final rule solicits public comment on also including other TRICARE-covered immunizations in the future for which retail network pharmacies will be authorized providers. As part of DoD preparations for a possible public health emergency involving H1N1 influenza this fall and winter, this is being issued as an interim final rule.

DATES: This interim final rule is effective December 10, 2009. Written

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comments received at the address indicated below by February 8, 2010 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, 1160 Defense Pentagon, Washington, DC 20301-1160.

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://regulations.gov as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: LtCol Thomas Bacon, TRICARE Management Activity, telephone (703) 681-2890.

SUPPLEMENTARY INFORMATION:

A. Background

In the last 5 years, registered pharmacists have played an increasing role in providing clinical services through the retail pharmacy venue. In 50 States, registered pharmacists are authorized to administer vaccines in a retail pharmacy setting. State Boards of Pharmacy are responsible for the training, oversight, and stipulating the conditions under which a pharmacist may administer a vaccine.

The DoD regulation implementing the TRICARE Pharmacy Benefit Program was written prior to this recent development. Therefore, although vaccines are covered under the TRICARE medical benefit, if administered by a pharmacist in a pharmacy the service is not currently covered by TRICARE. Inclusion of vaccines under the pharmacy benefit when provided by a TRICARE retail network pharmacy in accordance with state law, including when administered by a registered pharmacist, is the purpose of this regulation.

TRICARE recognizes that registered pharmacists are increasingly providing vaccine administration services in retail pharmacies. Although vaccines are a covered TRICARE medical benefit, when administered by a pharmacist claims cannot be adjudicated because vaccines are not covered under the pharmacy benefit and pharmacies are not recognized by regulation as authorized providers for the administration of vaccines. Currently, TRICARE beneficiaries who receive a vaccine administered by a pharmacist cannot be reimbursed for any out-of-pocket expenses. TRICARE would like to include vaccines under the pharmacy benefit when provided by a TRICARE retail network pharmacy when functioning within the scope of their state laws, including when administered by a registered pharmacist, to enable claims processing and reimbursement for services.

Adding immunizations to the pharmacy benefits program is an important public health initiative for TRICARE, making immunizations more readily available to beneficiaries. It is especially important as part of the Nation's public health preparations for a potential pandemic influenza, such as is threatened this fall and winter by a novel H1N1 virus strain. In view of potential shortages of H1N1 flu vaccine, military treatment facilities may not have sufficient vaccine for all high risk categories of beneficiaries, necessitating reliance on non-DoD sources of vaccine. Ensuring that TRICARE beneficiaries have ready access to vaccine supplies allocated to private sector pharmacies will facilitate making vaccine appropriately available to high risk groups of TRICARE beneficiaries.

B. Provisions of Rule

The rule amends sections 199.6 and 199.21 of the TRICARE regulation to authorize retail network pharmacies when functioning under the scope of their state laws to provide vaccines and immunizations to eligible beneficiaries as covered TRICARE pharmacy benefits. Under this interim final rule, this authorization applies immediately to three immunizations. The three immunizations are H1N1 vaccine, seasonal influenza vaccine, and pneumococcal vaccine. In addition, this interim final rule solicits public comment on the option of expanding this authorization in a final rule to also include all other TRICARE-covered immunizations.

C. Regulatory Procedures

Interim Final Rule

This is being issued as an interim final rule as part of DoD preparations for a potential public health emergency this fall and winter involving the H1N1 influenza virus. The normal practice of soliciting public comment before making a change to the regulation would in this case be contrary to the public interest because there is insufficient time to do so in anticipation for a potential public health emergency this fall and winter associated with a possible reemergence of a more virulent strain of H1N1 influenza virus. Thus, this rule will be effective from the date of publication. However, public comments are still invited and all such comments will be considered in the issuance of a final rule, expected later this year or early next.

Executive Order 12866, ``Regulatory Planning and Review''

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. The DoD has examined the economic and policy implications of this interim final rule and has concluded that it is not a significant regulatory action.

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

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 tribal governments, in aggregate, or by the private sector, of \$100 million or more 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 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 rule has no new information collection requirements.

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Executive Order 13132, ``Federalism''

This 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.

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Accordingly, 32 CFR part 199 is amended as follows:

PART 199--[AMENDED]

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

Authority: 5 U.S.C. 301; 10 U.S.C., Chapter 55.

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2. Section 199.6 is amended by revising paragraph (d)(3) to read as follows:

Sec. 199.6 TRICARE--authorized providers.

* * * * *

(d) * * *

(3) Pharmacies. Pharmacies must meet the applicable requirements of state law in the state in which the pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under Sec. 199.21 of this Part implementing the Pharmacy Benefits Program.

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3. Section 199.21 is amended by revising the heading of paragraph (h), and adding new paragraphs (h)(4) and (i)(2)(ii)(D) to read as follows:

Sec. 199.21 Pharmacy benefits program.

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(h) Obtaining pharmacy services under the retail network pharmacy benefits program. * * *

(4) Availability of vaccines/immunizations. This paragraph (h)(4) applies to the following three immunizations: H1N1 vaccine, seasonal influenza vaccine, and pneumococcal vaccine. 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 vaccines/immunizations authorized as preventive care under the basic program benefits of Sec. 199.4 of this Part, as well as such care authorized for Prime enrollees under the uniform HMO benefit of section 199.18. For Prime enrollees under the uniform HMO benefit, a referral is not required under paragraph (n)(2) of Sec. 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, or designee.

(i) * * *

(2) * * *

(ii) * * *

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

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Dated: December 3, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

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