

**§ 240.19b-4 Filings with respect to proposed rule changes by self-regulatory organizations.**

\* \* \* \* \*

(f) \* \* \*

(4) \* \* \*

(ii)(A) Primarily affects the futures clearing operations of the clearing agency with respect to futures that are not security futures; and

(B) Does not significantly affect any securities clearing operations of the clearing agency or any related rights or obligations of the clearing agency or persons using such service;

\* \* \* \* \*

**PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934**

■ 4. The general authority citation for part 249 continues to read in part as follows:

**Authority:** 15 U.S.C. 78a *et seq.* and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

\* \* \* \* \*

■ 5. Amend Form 19b-4 (referenced in § 249.819) by:

■ a. Amending paragraph (b)(iv) in Item 7 of the *General Instructions (Information to be Included in the Completed Form (“Form 19b-4 Information”))* as follows:

**Note:** The text of Form 19b-4 does not, and the amendments will not, appear in the Code of Federal Regulations.

**Form 19b-4**

\* \* \* \* \*

**GENERAL INSTRUCTIONS FOR FORM 19b-4**

\* \* \* \* \*

**Information to be Included in the Completed Form (“Form 19b-4 Information”)**

\* \* \* \* \*

**7. Basis for Summary Effectiveness Pursuant to Section 19(b)(3) or for Accelerated Effectiveness Pursuant to Section 19(b)(2) or Section 19(b)(7)(D)**

\* \* \* \* \*

(b) \* \* \*

(iv) effects a change in an existing service of a registered clearing agency that either (A)(1) does not adversely affect the safeguarding of securities or funds in the custody or control of the clearing agency or for which it is responsible and (2) does not significantly affect the respective rights or obligations of the clearing agency or persons using the service or (B)(1) primarily affects the futures clearing operations of the clearing agency with

respect to futures that are not security futures and (2) does not significantly affect any securities clearing operations of the clearing agency or any related rights or obligations of the clearing agency or persons using such service, and set forth the basis on which such designation is made,

\* \* \* \* \*

Dated: July 7, 2011.

By the Commission.

**Cathy H. Ahn,**

*Deputy Secretary.*

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**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**32 CFR Part 199**

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

**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:** Final rule.

**SUMMARY:** This final rule allows a TRICARE retail network pharmacy to be an authorized provider for the administration of TRICARE-covered vaccines in the retail pharmacy setting. The value of vaccines lies in the prevention of disease and reduced healthcare costs in the long term. When vaccines are made more readily accessible, a broader section of the population will receive them.

**DATES:** *Effective Date:* This final rule is effective August 12, 2011.

**FOR FURTHER INFORMATION CONTACT:** RADM Thomas McGinnis, TRICARE Management Activity, telephone (703) 681-2890.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

The value of vaccines lies in the prevention of disease and reduced healthcare costs in the long term. Vaccines are highly effective in preventing death and disability, and save billions of dollars in health costs annually. When vaccines are made more readily accessible, a broader section of the population will receive them. 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, vastly increasing the accessibility of many vaccines. State Boards of Pharmacy are responsible for the training, oversight, and stipulating the conditions under which a pharmacist may administer a vaccine.

The Department of Defense (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 except as provided for by the interim final rule published December 10, 2009 at 74 FR 65436. 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 except as provided for by the interim final rule. Currently, TRICARE beneficiaries who receive a vaccine administered by a pharmacist cannot be reimbursed for any out-of-pocket expenses except as provided for by the interim final rule. 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, such as was threatened last fall and winter by a novel H1N1 virus strain. Ensuring that TRICARE beneficiaries have ready access to vaccine supplies allocated to private sector pharmacies will facilitate making vaccines appropriately available to high risk groups of TRICARE

beneficiaries. The vaccines to be made available at network pharmacies under this final rule are those authorized as preventive care under the TRICARE basic program benefits at 32 CFR 199.4 and those authorized for Prime enrollees at 32 CFR 199.18, *i.e.*, immunizations for individuals age six and older, as recommended by the Centers for Disease Control and Prevention (CDC), and immunizations provided when required in the case of dependents of active duty military personnel who are traveling outside the United States as a result of an active duty member's assignment and such travel is being performed under orders issued by a Uniformed Service. Immunizations included will be those recommended by the CDC and published in the Morbidity and Mortality Weekly Report (MMWR). To find information on recommended vaccinations, TRICARE will refer beneficiaries to <http://www.cdc.gov/vaccines> or <http://www.tricare.mil/pharmacy>. TRICARE will also encourage beneficiaries to speak with their doctor or pharmacist about which vaccinations may be appropriate for them.

An Independent Government Cost Estimate (IGCE) shows an additional cost to the Defense Health Program (DHP) of approximately \$4M annually. This cost is primarily driven from beneficiaries who were not receiving the vaccines previously, or from beneficiaries who were paying out-of-pocket to get the vaccines. For the first six months following publication of the interim final rule, 18,361 vaccines were administered under the pharmacy benefits program at a cost of \$298,513.19. Had those vaccines been administered under the medical benefit, the cost to TRICARE would have been \$1.8M. These savings come both from the lower cost of the vaccines procured under the pharmacy benefits program rather than under the medical benefit which uses the Medicare payment allowance and a shift from the overall higher costs of obtaining a vaccine through a physician office visit. Expanding the number of vaccines available under the pharmacy benefits program from the three listed in the original interim final rule (seasonal influenza, H1N1 vaccine and pneumococcal vaccine) to all of those covered under the DoD's preventive care program, will result in increased savings over the cost of administering those vaccines under the medical benefit. In addition to the lower vaccine costs and costs of administration through the pharmacy benefits program, there is an anticipated cost savings which will

result from not having to treat beneficiaries who, due to a higher expected vaccination rate, will not develop the illnesses for which the vaccines were administered. For example an IGCE showed DHP savings of over \$600,000 annually in medical costs that would have been incurred in treating beneficiaries for influenza but were not because increased availability of the flu vaccine led to more beneficiaries being vaccinated.

Although the DoD is normally required to follow the same reimbursement methodologies as Medicare, there is an exception allowed when it is not practicable to do so. In calculating the administration fee for injecting these vaccines, the Department has determined that it is not practicable to follow Medicare. Medicare Part B preventive services vaccinations are limited to invasive pneumococcal disease, hepatitis B, and influenza. Medicare's administration fee schedules are adjusted for each Medicare payment locality. Therefore, there is a variation in the Medicare administration payment amount nationwide. The TRICARE pharmacy benefits program will provide many more vaccines than those available under Medicare Part B, and the Medicare rates vary by its various regions and the contractors who administer the programs in those regions. However, TRICARE has only one network retail pharmacy manager and to require the one network administrator to have various rates for the small number of drugs covered by Medicare is neither administratively feasible nor cost effective. To analyze administrative costs of the program, an IGCE compared the Medicare administration fee for the vaccines covered under Medicare Part B to the nationwide administration fees negotiated by the TRICARE pharmacy benefits manager. The results of the IGCE show the rates available to TRICARE will be lower than the rates reimbursed by Medicare.

#### B. Provisions of the Interim Final Rule

The interim final rule amended 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 the interim final rule, this authorization applied immediately to three immunizations. The three immunizations are H1N1 vaccine, seasonal influenza vaccine, and pneumococcal vaccine. In addition, the interim final rule solicited public

comment on also including other TRICARE-covered immunizations in the future for which retail network pharmacies will be authorized providers.

#### C. Public Comments

The interim final rule, published in the **Federal Register** December 10, 2009, provided for a 60-day comment period. DoD received seven public comments: four comments from DoD beneficiaries; two comments from professional pharmacy associations; and, one comment from a retail pharmacy chain. Comments are discussed below.

##### 1. DoD Beneficiary Comments (4 Total)

###### a. Co-Payments

*Comments:* Two beneficiary comments were in favor of making vaccines available in retail pharmacies and asked if there would be a co-pay.

*Response:* The final rule makes no change to the interim final rule provision that there will be \$0.00 co-payment for vaccines/immunizations authorized as preventive care for eligible beneficiaries.

###### b. Expand To Include Other Vaccines

*Comments:* Two beneficiary comments were in favor of making vaccine available in retail pharmacies and suggested expanding the program to include other vaccines.

*Response:* The final rule authorizes retail network pharmacies when functioning under the scope of their state laws to provide all TRICARE-covered vaccines and immunizations.

##### 2. Professional Pharmacy Associations (2)

*Comments:* Both associations highly support and applaud DoD in recognizing that services provided by pharmacists are essential in meeting the healthcare needs of all communities, especially those of TRICARE beneficiaries. Both associations were favorable to expanding the role of pharmacists, including as a community point of service for vaccine administration. Both agree that this rule brings the DoD pharmacy program in line with other insurers that have covered pharmacy/pharmacist administered vaccinations for years.

*Response:* DoD agrees.

##### 3. Retail Pharmacy Chain (1)

*Comment:* A retail chain with 211 pharmacies in the state of Texas stated that over 70% of its pharmacists are active immunizers and have been actively providing this service for over 10 years. The chain strongly supports the expansion of the program to include

other vaccines and commends the Department for waiving cost shares.

*Response:* DoD agrees.

#### D. Provisions of Final Rule

The final 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 TRICARE authorized vaccines and immunizations to eligible beneficiaries as covered TRICARE pharmacy benefits.

#### E. Regulatory Procedures

*Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"*

Executive Order 12866 and 13563 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 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.

*Section 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 final rule does include information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3511). The information collection has been approved with the Office of Management and Budget control number 0720-0032.

*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.

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

#### § 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 § 199.21 of this part implementing the Pharmacy Benefits Program.

\* \* \* \* \*

■ 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:

#### § 199.21 Pharmacy benefits program.

\* \* \* \* \*

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

(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.

(i) \* \* \*

(2) \* \* \*

(ii) \* \* \*

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

\* \* \* \* \*

Dated: July 5, 2011.

**Patricia L. Toppings,**  
*OSD Federal Register Liaison Officer,*  
*Department of Defense.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

Docket No. USCG-2011-0264

RIN 1625-AA00

#### Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is amending 33 CFR 165.929 Safety Zones; Annual Events requiring safety zones in the Captain of the Port Lake Michigan zone. This rule will amend, establish, or delete the rules that restrict vessels from portions of water areas during events that pose a hazard to public safety. The safety zones amended or established by