the performance of a radiochemical identity/purity test or prevents the determination of the product's specific activity.

(3) You may not release another batch of the PET drug product until you have corrected the problem concerning the malfunction of analytical equipment and completed the omitted finished-product test.

§ 212.71 What actions must I take if a batch of PET drug product does not conform to specifications?

(a) *Rejection of nonconforming product.* You must reject a batch of a PET drug product that does not conform to specifications. You must have and follow procedures to identify and segregate the product to avoid mix-ups. You must have and follow procedures to investigate the cause(s) of the nonconforming product. The investigation must include, but is not limited to, examination of processes, operations, records, complaints, and any other relevant sources of information concerning the nonconforming product.

(b) *Investigation.* You must document the investigation of a PET drug product that does not meet specifications, including the results of the investigation and what happened to the rejected PET drug product.

(c) *Correction of problems.* You must take action to correct any identified problems to prevent recurrence of a nonconforming product or other quality problem.

(d) *Reprocessing.* If appropriate, you may reprocess a batch of a PET drug product that does not conform to specifications. If material that does not meet acceptance criteria is reprocessed, you must follow procedures stated in the product's approved application and the finished product must conform to specifications, except for sterility, before final release.

Subpart I—Packaging and Labeling

§ 212.80 What are the requirements associated with labeling and packaging PET drug products?

(a) A PET drug product must be suitably labeled and packaged to protect the product from alteration, contamination, and damage during the established conditions of shipping, distribution, handling, and use.

(b) Labels must be legible and applied so as to remain legible and affixed during the established conditions of processing, storage, handling, distribution, and use.

(c) All information stated on each label must also be contained in each batch production record.

(d) Labeling and packaging operations must be controlled to prevent labeling and product mix-ups.

Subpart J—Distribution

§ 212.90 What actions must I take to control the distribution of PET drug products?

(a) *Written distribution procedures.* You must establish, maintain, and follow written procedures for the control of distribution of PET drug products shipped from the PET drug production facility to ensure that the method of shipping chosen will not adversely affect the identity, purity, or quality of the PET drug product.

(b) *Distribution records.* You must maintain distribution records for each PET drug product that include or refer to the following:

(1) The name, address, and telephone number of the receiving facility that received each batch of a PET drug product;

(2) The name and quantity of the PET drug product shipped;

(3) The lot number, control number, or batch number for the PET drug product shipped; and

(4) The date and time you shipped the PET drug product.

Subpart K—Complaint Handling

§ 212.100 What do I do if I receive a complaint about a PET drug product produced at my facility?

(a) *Written complaint procedures.* You must develop and follow written procedures for the receipt and handling of all complaints concerning the quality or purity of, or possible adverse reactions to, a PET drug product.

(b) *Complaint review.* The procedures must include review by a designated person of any complaint involving the possible failure of a PET drug product to meet any of its specifications and an investigation to determine the cause of the failure.

(c) *Complaint records.* A written record of each complaint must be maintained in a file designated for PET drug product complaints. The record must include the name and strength of the PET drug product, the batch number, the name of the complainant, the date the complaint was received, the nature of the complaint, and the response to the complaint. It must also include the findings of any investigation and followup.

(d) *Returned products.* A PET drug product that is returned because of a complaint or for any other reason may not be reprocessed and must be destroyed in accordance with applicable Federal and State law.

Subpart L—Records

§ 212.110 How must I maintain records of my production of PET drugs?

(a) *Record availability.* Records must be maintained at the PET drug production facility or another location that is reasonably accessible to responsible officials of the production facility and to employees of FDA designated to perform inspections.

(b) *Record quality.* All records, including those not stored at the inspected establishment, must be legible, stored to prevent deterioration or loss, and readily available for review and copying by FDA employees.

(c) *Record retention period.* You must maintain all records and documentation referenced in this part for a period of at least 1 year from the date of final release, including conditional final release, of a PET drug product.

Dated: December 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–29285 Filed 12–9–09; 8:45 am]

BILLING CODE 4160–01–S

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

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 tribunal 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.

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.* 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 § 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 § 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.

* * * * *

Dated: December 3, 2009.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E9–29432 Filed 12–9–09; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2009–1014]

RIN 1625–AA00

Safety Zone, Chicago Harbor, Navy Pier Southeast, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Navy Pier Southeast Safety Zone in Chicago Harbor from December 4, 2009, through January 1, 2010. This action is necessary and intended to ensure safety of life on the navigable waters immediately prior to, during, and immediately after fireworks events. This rule will establish restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after fireworks events. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port Lake Michigan.

DATES: The regulations in 33 CFR 165.931 will be enforced on December 4, 2009, from 7 p.m. through 7:30 p.m.; on December 31, 2009, from 8 p.m. through 8:30 p.m.; on December 31, 2009, from 11:45 p.m. through 12:30 a.m. on January 1, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email BM1 Adam Kraft, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at 414–747–7154, e-mail *Adam.D.Kraft@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zone, Chicago Harbor, Navy Pier Southeast, Chicago, IL, in 33 CFR 165.931, for the following events:

(1) *Navy Pier Fireworks:* on December 4, 2009, from 7 p.m. through 7:30 p.m.; on December 31, 2009, from 8 p.m. through 8:30 p.m.; on December 31, 2009, from 11:45 p.m. through 12:30 a.m. on January 1, 2010.

All vessels must obtain permission from the Captain of the Port or a designated representative to enter, move within, or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port or a designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.931, Safety Zone, Chicago Harbor, Navy Pier Southeast, Chicago, IL and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via broadcast Notice to Mariners or Local Notice to Mariners. The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. If the Captain of the Port determines that the safety zone need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the safety zone. The Captain of the Port or their on-scene representative may be contacted via VHF–FM Channel 16.

Dated: November 30, 2009.

L. Barndt,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. E9–29416 Filed 12–9–09; 8:45 am]

BILLING CODE 9110–04–P