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 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.


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
This 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 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.


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:


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.

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 zone 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