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 follow-up.

(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.


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.
ADDRESS(es): 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
SUPPLEMENTARY INFORMATION:
MAIL: Federal Docket Management
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
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
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:


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.

* * * * *


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.

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