Program. This preauthorization requirement does not apply to other points of service under the Pharmacy Benefits Program.

(iii) For purposes of this paragraph (q)(2), a covered drug is a drug that is a covered drug under 38 U.S.C. 8126, but does not include:

(A) A drug that is not a covered drug under 38 U.S.C. 8126;

(B) A drug provided under a prescription that is not covered by 10 U.S.C. 1074(f); or

(C) A drug that is not provided through a retail network pharmacy under this section;

(D) A drug provided under a prescription which the TRICARE Pharmacy Benefits Program is the second payer under paragraph (m) of this section;

(E) A drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act; or

(F) Any other exception for a drug, consistent with law, established by the Director, TMA.

(iv) The requirement of this paragraph (q)(2) may, upon the recommendation of the Pharmacy and Therapeutics Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement referred to in paragraph (q)(1) that all covered TRICARE retail network pharmacy prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements under this paragraph (q)(2).

(3) Refund procedures. (i) Refund procedures to ensure that pharmaceuticals paid for by the DoD that are provided by retail network pharmacies under the pharmacy benefits program are subject to the pricing standards referred to in paragraph (q)(1) of this section shall be established. Such procedures may be established as part of the agreement referred to in paragraph (q)(2), or in a separate agreement, or pursuant to § 199.11.

(ii) The refund procedures referred to in paragraph (q)(3)(i) of this section shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. Such procedures shall provide the manufacturer with a 30-day period from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the annual non-FAMP from which it was derived will be applicable to all prescriptions filled during the calendar year.

(iii) A refund due under this paragraph (q) is subject to § 199.11 of this part and will be treated as an erroneous payment under that section.

(A) A manufacturer may under section 199.11 of this part request waiver or compromise of a refund amount due under 10 U.S.C. 1074(f) and this paragraph (q).

(B) During the pendency of any request for waiver or compromise under paragraph (q)(3)(iii)(A) of this section, a manufacturer’s written agreement under paragraph (q)(2) shall be deemed to exclude the subject of the request for waiver or compromise. In such cases the agreement, if otherwise sufficient for the purpose of the condition referred to in paragraph (q)(2), will continue to be sufficient for that purpose. Further, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor a request or an agreement for purposes of paragraph (q)(4).

(C) In addition to the criteria established in § 199.11, a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program.

(iv) In the case of disputes by the manufacturer of the accuracy of TMA’s utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute in accordance with procedures established by the Director, TMA. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under section 199.11 of this part. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge from the date payment of the amount was initially due, consistent with section 199.11 of this part.

(4) Remedies. In the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law.

(5) Beneficiary transition provisions. In cases in which a pharmaceutical is removed from the uniform formulary or designated for preauthorization under paragraph (q)(2) of this section, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the uniform formulary.


Morgan F. Park,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0926]

Drawbridge Operation Regulations; Hackensack River, Jersey City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 1 & 9 Lincoln Highway Bridge across the Hackensack River, mile 1.8, at Jersey City, New Jersey. The deviation allows the bridge owner to require a two-hour advance notice for openings for two and a half months and several short term bridge closures to facilitate bridge painting operations.

DATES: This deviation is effective with constructive notice from October 15, 2010 through December 15, 2010, and for enforcement with actual notice from October 4, 2010 through October 15, 2010.
ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0926 and are available online at http://www.regulations.gov, inserting USCG–2010–0926 in the “Keyword” and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Joe Arca, Project Officer, First Coast Guard District, joe.arca@uscg.mil, telephone (212) 668–7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Route 1 & 9 Lincoln Highway Bridge, across the Hackensack River, mile 1.8, at Jersey City, New Jersey, has a vertical clearance in the closed position of 35 feet at mean high water and 40 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.5.

The waterway is primarily used by deep draft tankers, tugs and barge units.

The owner of the bridge, New Jersey Department of Transportation, requested a second temporary deviation from the regulations to facilitate scheduled bridge painting operations at the bridge. We issued a previous temporary deviation for this bridge painting project which was in effect from April 1, 2010 through September 15, 2010; however, due to weather related delays additional time is needed to complete the bridge painting before the cold winter climate forces suspension of painting operations.

Waterway users were advised of the requested bridge advance notice and closure periods and offered no objection.

Under this temporary deviation the Route 1 & 9 Lincoln Highway Bridge shall require a two-hour advance notice for bridge openings from October 1, 2010 through December 15, 2010, by calling the number posted at the bridge.

In addition, the bridge owner requested several bridge closures of short duration to facilitate bridge painting operations.

The exact bridge closure dates are not known at this time; however, once determined, we will publish the closure dates in the Local Notice to Mariners two weeks in advance of implementation and also issue a safety information broadcast twenty-four hours in advance of the implementation.

Vessels able to pass under the closed draw may do so at all times.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Gary Kassof, Bridge Program Manager, First Coast Guard District.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 et seq.; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the Federal Register.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA’s initial flood insurance map of the community as having flood-prone areas (section 202(a)(6) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer