

Rules and Regulations

Federal Register

Vol. 78, No. 63

Tuesday, April 2, 2013

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. FDA-2013-N-0011]

Change of Address; Biologics License Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update the address for applicants to submit biologics license applications (BLAs) and BLA amendments and supplements regulated by the Center for Drug Evaluation and Research (CDER). This action is being taken to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective April 2, 2013.

FOR FURTHER INFORMATION CONTACT:

Scott E. Zeiss, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1120, Silver Spring, MD 20993-0002, 301-796-0639.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR 600.2(b) to update the address for applicants to submit BLAs and BLA amendments and supplements regulated by CDER. The new address for all these submissions is CDER Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901B Ammendale Rd., Beltsville, MD 20705. This action is being taken to ensure accuracy and clarity in the Agency's regulations.

Publication of this document constitutes final action on these changes

under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update an address for the submission of BLAs and BLA amendments and supplements.

List of Subjects for 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

§ 600.2 [Amended]

■ 2. Section 600.2 is amended in the first sentence of paragraph (b) by removing "CDER Therapeutic Biological Products Document Room" and adding in its place "CDER Central Document Room", and by removing "12229 Wilkins Ave., Rockville, MD 20852" and adding in its place "5901B Ammendale Rd., Beltsville, MD 20705".

Dated: March 27, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013-07578 Filed 4-1-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2013-0142]

Drawbridge Operation Regulations; China Basin, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating

schedule that governs the Third Street Drawbridge across the China Basin, mile 0.0, at San Francisco, CA. The deviation is necessary to allow the public to cross the bridge to participate in the scheduled CycleSF, a community event. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective from 6 a.m. until 10 a.m. on April 28, 2013.

ADDRESSES: The docket for this deviation, [USCG-2013-0142], is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 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 temporary deviation, call or email David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510-437-3516, email David.H.Sulouff@uscg.mil. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION: The City of San Francisco requested a temporary change to the operation of the Third Street Drawbridge, mile 0.0, over China Basin, at San Francisco, CA. The Third Street Drawbridge navigation span provides a vertical clearance of 7 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal if at least one hour notice is given as required by 33 CFR 117.149. Navigation on the waterway is recreational.

The drawspan will be secured in the closed-to-navigation position 6 a.m. until 10 a.m. on April 28, 2013, to allow participants in the CycleSF to cross the bridge during the event. This temporary deviation has been coordinated with the waterway users. No objections to the proposed temporary deviation were raised. The drawspan can be operated upon one hour advance notice for emergencies requiring the passage of waterway traffic.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time. In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 21, 2013.

D.H. Sulouff,

Bridge Section Chief, Eleventh Coast Guard District.

[FR Doc. 2013-07572 Filed 4-1-13; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AO01

Grants for Transportation of Veterans in Highly Rural Areas

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulations to establish a new program to provide grants to eligible entities to assist veterans in highly rural areas through innovative transportation services to travel to VA medical centers, and to otherwise assist in providing transportation services in connection with the provision of VA medical care to these veterans, in compliance with section 307 of title III of the Caregivers and Veterans Omnibus Health Services Act of 2010. This final rule establishes procedures for evaluating grant applications under the new grant program, and otherwise administering the new grant program.

DATES: *Effective date:* This rule is effective May 2, 2013.

FOR FURTHER INFORMATION CONTACT:

David Riley, Director, Veterans Transportation Service, Chief Business Office (10NB), Veterans Health Administration, Department of Veterans Affairs, 2957 Clairmont Road, Atlanta, GA 30329, (404) 828-5601. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 30, 2011, VA published in the *Federal Register* (76 FR 82212) a proposal to amend VA regulations to establish a grant program to provide innovative transportation options to veterans in highly rural areas, to comply with section 307 of title III of the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law

111-163. Subsection (a) of section 307 mandates that VA award grants to only State veterans service agencies (SVSAs) and Veterans Service Organization (VSOs) to assist veterans in highly rural areas to travel to VA medical centers, and to otherwise assist in providing transportation in connection with the provision of VA medical care to these veterans. This final rule establishes the grant program in accordance with subsection (a) of section 307, and establishes procedures for evaluating grant applications and otherwise administering the grant program in accordance with subsection (b) of section 307.

Interested persons were invited to submit comments to the proposed rule on or before February 28, 2012, and we received 17 comments. All of the issues raised by the commenters can be grouped together by similar topic, and we have organized our discussion of the comments accordingly. For the reasons set forth in the proposed rule and below, we are adopting the proposed rule as final, with changes to §§ 17.701, 17.703, 17.705, 17.715, and 17.725 and the authority citations following the regulations in this rulemaking.

Comments Regarding the Limitation on Entities That Are Eligible To Receive Grants

Multiple commenters objected to the proposed rule's limitation that only VSOs and SVSAs may receive grants. These commenters contended that this limitation would block many existing transportation providers from receiving grants to expand current veterans' transportation services, to the detriment of veterans generally. Commenters asserted that making grants available to any existing transportation provider would ensure that grants would be used more effectively because VSOs and SVSAs that receive grants would only be duplicating transportation services already offered to veterans by existing providers, and because VSOs and SVSAs do not have the expertise of existing transportation providers to access a particular area or transport that area's veterans. We make no changes to the rule based on these comments, because grantees are limited by section 307 to VSOs and SVSAs. Subsection (a)(2) of section 307 identifies as eligible grant recipients "State veterans service agencies" and "Veterans service organizations." Subsection (a)(3) of section 307 further states that "[a] State veterans service agency or veterans service organization" may use grant funds for specified purposes. We interpret this statutory language to bar

VA from awarding grants to any entity other than a VSO or SVSA.

To more specifically address commenter concerns regarding duplicated services and lack of grantee expertise, we note that most commenters seemed to assume that VSOs and SVSAs that receive grants would not themselves be existing transportation providers. However, we know of several VSOs and SVSAs that provide transportation services. Moreover, the rule contains scoring criteria to reward coordination between grantees and other transportation providers (including existing providers that may not qualify to receive grants), and rewarding this type of coordination assists in addressing the general concerns of duplicated services and lack of grantee expertise. See § 17.705(a)(3). Discussion of these coordination criteria, as well as discussion of why VSOs and SVSAs would not merely be duplicating existing transportation services, are provided in greater detail in the next section of this document. Generally, grantees may use grants to expand or augment the transportation services offered by transportation providers that may not qualify as grantees under the rule, or otherwise may use such entities to provide the transportation assistance that is established in a grantee's program, as long as all other criteria of the rule are met.

One commenter specifically asserted that section 307 could be interpreted in an "innovative" manner to allow a grant award to an organization such as a county-level agency within a State that is delegated responsibilities to serve veterans by an SVSA, based on the following language from section 307: "The Secretary of Veterans Affairs shall establish a grant program to provide innovative transportation options to veterans in highly rural areas." Public Law 111-163, sec. 307(a)(1). We interpret the term "innovative" in section 307(a)(1), however, only as a modifier to describe the types of transportation options that may be provided to veterans in highly rural areas. We do not interpret the term as having any effect regarding the two defined eligible entities that may receive grants under section 307. The plain meaning of a "State veterans service agency" considers only State-level entities, and not a county agency within a State. However, under the same rationale provided above, this rule does not prevent an SVSA from using grant funds to administer transportation assistance through a county-level agency to carry out the objectives of the SVSA's grant application.