

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 48

[TD 9604]

RIN 1545-BJ44

Taxable Medical Devices; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting Amendment.

SUMMARY: This document contains corrections to final regulations (TD 9604) that were published in the **Federal Register** on Friday, December 7, 2012 (77 FR 72924). The final regulations provide guidance on the excise tax imposed on the sale of certain medical devices, enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act.

DATES: This correction is effective on March 13, 2013 and is applicable after December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Natalie Payne, Michael Beker, or Stephanie Bland, at (202) 622-3130 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9604) that are the subject of this correction is under section 4191 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9604) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 48

Excise taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 48 is corrected by making the following correcting amendments:

PART 48—MANUFACTURERS AND RETAILERS EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 48 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 48.4191-2 is amended by revising:

■ 1. The second sentence of paragraph (b)(2).

■ 2. The last sentence of paragraph (b)(2)(iv) *Example 5.*, and *Example 6.*

■ 3. Paragraph (b)(2)(iv) *Example 7.*
 ■ 4. The last sentence of paragraph (b)(2)(iv) *Example 8.*, *Example 11.*, and *Example 13.*

The revisions read as follows:

§ 48.4191-2 Taxable medical device.

* * * * *

(b) * * *

(2) * * * A device will be considered to be of a type that is generally purchased by the general public at retail for individual use if it is regularly available for purchase and use by individual consumers who are not medical professionals, and if the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional. * * *

* * * * *

(iv) * * *

Example 5. * * * Based on the totality of the facts and circumstances, the mobile x-ray systems are not devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 6. * * * Accordingly, the pregnancy test kits are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 7. X manufactures blood glucose monitors, blood glucose test strips, and lancets. X sells the blood glucose monitors, test strips, and lancets to distributors Y and Z, which, in turn, sell the monitors, test strips, and lancets to medical institutions and offices, medical professionals, and retail businesses. The FDA requires manufacturers of blood glucose monitors, test strips, and lancets to list the items as devices with the FDA. The FDA classifies the blood glucose monitors under 21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices) and product code NBW. The FDA classifies the test strips under 21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices) and product code NBW. The FDA classifies the lancets under 21 CFR part 878 (General and Plastic Surgery Devices) and product code FMK.

The blood glucose monitors and test strips are included in the FDA's online IVD Home Use Lab Tests (Over-the-Counter Tests) database. Therefore, the blood glucose monitors and test strips fall within the safe harbor set forth in paragraph (b)(2)(iii)(A) of this section. Further, the FDA product code name for NBW is "System, Test, Blood Glucose, Over the Counter." Therefore, the blood glucose monitors and test strips also fall within the safe harbor set forth in paragraph (b)(2)(iii)(C) of this section.

In addition, the lancets are supplies necessary for the effective use of DME as described in section 110.3 of chapter 15 of the Medicare Policy Benefit Manual. Therefore, the lancets fall within the safe harbor set forth in paragraph (b)(2)(iii)(D)(5) of this section.

Accordingly, the blood glucose monitors, test strips, and lancets are devices that are of a type that are generally purchased by the general public at retail for individual use.

Example 8. * * * Accordingly, both the single axis endoskeletal knee shin systems manufactured by X and the prosthetic legs made by Y are devices that are of a type that are generally purchased by the general public at retail for individual use.

* * * * *

Example 11. * * * Accordingly, the urinary ileostomy bags are devices that are of a type that are generally purchased by the general public at retail for individual use.

* * * * *

Example 13. * * * Based on the totality of the facts and circumstances, the NMRI systems are not devices that are of a type that are generally purchased by the general public at retail for individual use.

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■ **Par. 3.** Section 48.4216(c)-1 is amended by revising paragraph (e)(1) to read as follows:

§ 48.4216(c)-1 Computation of tax on leases and installment sales.

* * * * *

(e) * * *

(1) *General rule.* Payments made on or after January 1, 2013, pursuant to a contract for the lease, installment sale, or sale on credit of a taxable medical device that was entered into on or after March 30, 2010, are subject to tax under section 4191. The provisions of sections 4216(c) and 4217, paragraphs (a), (b), and (c) of this section, and § 48.4217-2 apply.

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LaNita VanDyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2013-05703 Filed 3-12-13; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2013-0044]

Drawbridge Operation Regulations; Sacramento River, Sacramento, 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 Tower Drawbridge across Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the community to participate in the Ninth Annual Shamrock footrace. This deviation allows the bridge to remain in

the closed-to-navigation position during the event.

DATES: This deviation is effective from 7:30 a.m. to 1:05 p.m. on March 17, 2013.

ADDRESSES: The docket for this deviation, [USCG–2013–0044], 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 rule, 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 California Department of Transportation has requested a temporary change to the operation of the Tower Drawbridge, mile 59.0, over Sacramento River, at Sacramento, CA. The Tower Drawbridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. As required by 33 CFR 117.189(a), the draw opens on signal from May 1 through October 31 from 6 a.m. to 10 p.m. and, from November 1 through April 30 from 9 a.m. to 5 p.m. At all other times the draw shall open on signal if at least four hours notice is given. Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 7:30 a.m. to 1:05 p.m. on March 17, 2013, to allow the community to participate in the Ninth Annual Shamrock footrace. This temporary deviation has been coordinated with waterway users. There are no scheduled river boat cruises or anticipated levee maintenance during this deviation period. No objections to the proposed temporary deviation were raised. Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time. In the event of an emergency the drawspan can be opened without delay.

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: February 28, 2013.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2013–05712 Filed 3–12–13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2013–0038]

Drawbridge Operation Regulations; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating regulation that governs the Tower Drawbridge across the Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the community to participate in the First Annual “Biggest Loser” 5K walk and run event. This deviation allows the bridge to remain in the closed-to-navigation position during the event.

DATES: This deviation is effective from 7:30 a.m. to 9:30 a.m. on March 16, 2013.

ADDRESSES: The docket for this deviation, [USCG–2013–0038], 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 rule, 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 California Department of Transportation has requested a temporary change to the

operation of the Tower Drawbridge, mile 59.0, over Sacramento River, at Sacramento, CA. The Tower Drawbridge navigation span provides a vertical clearance of 30 feet above Mean High Water in the closed-to-navigation position. As required by 33 CFR 117.189(a), the draw opens on signal from May 1 through October 31 from 6 a.m. to 10 p.m., and from November 1 through April 30 from 9 a.m. to 5 p.m. At all other times the draw shall open on signal if at least four hours notice is given. Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 7:30 a.m. to 9:30 a.m. on March 16, 2013, to allow the community to participate in the First Annual “Biggest Loser” 5K walk and run event. This temporary deviation has been coordinated with waterway users. There are no scheduled river boat cruises or anticipated levee maintenance during this deviation period. No objections to the proposed temporary deviation were raised. Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time. In the event of an emergency the drawspan can be opened without delay.

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: February 25, 2013.

D.H. Sulouff,

District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2013–05713 Filed 3–12–13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2013–0123]

Drawbridge Operation Regulation; Willamette River, Portland, OR

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 Broadway Bridge across the Willamette River, mile 11.7, at Portland, OR. This deviation is necessary to accommodate the Race for the Roses and the Bridge to Brews Run