[4830-01-P]

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 **[INSERT DATE OF PUBLICATION OF THIS DOCUMENT IN THE FEDERAL REGISTER ]** 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--MANUFATURERS 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. * * *

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(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.

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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.

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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.

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(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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