

**Office of Chief Counsel
Internal Revenue Service
memorandum**

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to: Barbara J. Fiebich
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from: Charles J. Langley, Jr.
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(Passthroughs & Special Industries)

subject: Manufacturer Provision of Specialized Taxable Medical Device

This memorandum responds to your request for assistance on the proper treatment of a manufacturer's temporary provision of specialized surgical instruments as part of the sale of a taxable medical device. This advice may not be used or cited as precedent.

ISSUE:

Whether a manufacturer's temporary provision of a surgical instrument that is a taxable medical device to a medical device purchaser, at no additional charge, is a lease under sections 4216 and 4217 of the Internal Revenue Code.

CONCLUSION:

A manufacturer's temporary provision of a surgical instrument that is a taxable medical device to a medical device purchaser, at no additional charge, is a lease under sections 4216 and 4217. The portion of the sale price of the taxable medical device that is attributable to the manufacturer's provision of the surgical instrument to the device purchaser is a lease payment and is taxed as a sale at the rate of tax in effect as of the date of payment.

FACTS:

Manufacturer (X) manufactures a taxable medical device within the meaning of section 4191 (Device). Additionally, X manufactures a surgical instrument that is also a taxable medical device (Instrument), which is used to implant Device in the patient. Instrument

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is necessary for the surgical implantation of Device and has no medical use other than to implant Device.

X sells Device to hospitals and surgical facilities. X does not sell Instrument in the ordinary course of trade. X provides Instrument only to purchasers of Device, which then have exclusive possession and use of Instrument for a period of time. The title to Instrument remains with X and Instrument is ultimately returned to X. The invoice for Device does not include a separate charge for use of Instrument and X does not provide a separate invoice for Instrument.

LAW:

Section 4191(a) imposes a tax on the sale of any taxable medical device by the manufacturer, producer, or importer of 2.3 percent of the price for which the device was sold.

Under section 4216(c), in the case of a lease (other than a lease to which section 4217(b) applies), there shall be paid upon each payment with respect to the article a percentage of such payment equal to the rate of tax in effect on the date such payment is due.

Section 4217(a) provides that for purposes of chapter 32, the lease of an article (including any renewal or any extension of a lease or any subsequent lease of such article) by the manufacturer, producer or importer shall be considered a sale of such article.

Under § 48.4216(c)-1(a) of the Manufacturers and Retailers Excise Tax Regulations, when a taxable article is leased by a manufacturer, producer, or importer, liability for tax is incurred, except as provided by section 4217(b) and § 48.4217-2, on each payment made with respect to such lease. Tax is payable on each lease payment as long as the article is leased by the manufacturer, producer, or importer. The tax payable with respect to each lease payment is a percentage of each payment based on the rate of tax, if any, in effect on the date the lease payment is due. If the article is subsequently sold by the manufacturer, producer, or importer, the tax applies also to such sale, without regard to the tax paid when the article was leased. For definition of the term "lease," see paragraph (a) of § 48.4217-1(a).

Section 48.4217-1 defines the term "lease" to mean a contract or agreement, written or verbal, which gives the lessee an exclusive, continuous right to the possession or use of a particular article for a period of time. The term includes any renewal or extension of a lease or any subsequent lease of the article.

Section 48.4217-2(a) explains that section 4217(b) provides for a limitation on the amount of tax that shall apply to the lease, any renewal, or further lease, of an article which, if sold, would be subject to tax on the basis of sale price. Such limitation on the

amount of the tax applies with respect to the lease of an article only if, at the time of making the lease, the lessor is engaged in the business of selling in arm's length transactions the same type and model of article. In the case of a lease to which section 4217(b) does not apply, tax shall be computed and paid as provided in section 4216(c) and § 48.4216(c)-1(a).

ANALYSIS:

Section 48.4217-1 defines the term "lease" to mean a contract or agreement, written or verbal, which gives the lessee an exclusive, continuous right to the possession or use of a particular article for a period of time. Here, X provides to customers that purchase Device the exclusive right to possess and use Instrument for a period of time. However, title to Instrument remains with X and Instrument is ultimately returned to X. Therefore, the possession and use of Instrument falls within the definition of a lease. X provides Instrument to customers as part of the consideration for the purchase price of Device. Thus, a portion of the Device purchase price is attributable to the purchaser's possession and use of Instrument.

Instrument is necessary for the surgical implantation of Device and has no medical use other than to implant Device. X receives no separate or additional consideration from a Device purchaser in exchange for the possession and use of Instrument. Accordingly, the Device purchase price is consideration for both the Device purchase and Instrument lease, and a portion of the purchase price of Device is attributable to the purchaser's lease of Instrument. Under section 4216(c) and § 48.4216(c)-1(a), tax is payable on such lease payment at a rate equal to the rate of tax in effect on the date such payment is due.

Section 4217(b) provides for a limitation on the amount of tax that shall apply to the lease of an article only if, at the time of making the lease, the lessor is engaged in the business of selling in arm's length transactions the same type and model of article. X is not in the business of selling Instrument. Thus, the section 4217(b) limitation does not apply.

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Please call (202) 317-6855 if you have any further questions.