the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VI. Codification of Orders

Prior to the amendments by FDASIA, section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found substantially equivalent to preamendments devices. Section 515(b) of the FD&C Act, as amended by FDASIA, provides for FDA to require approval of an application for premarket approval for such devices by issuing a final order following the issuance of a proposed order in the Federal Register. FDA will continue to codify the requirement for an application for premarket approval in the Code of Federal Regulations (CFR). Therefore, under section 515(b)(1) of the FD&C Act, as amended by FDASIA, in this final order, FDA is requiring approval of an application for premarket approval for total MoM semi-constrained hip joint systems, which include the following two specific preamendments class III devices: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis; and the Agency is making the language in 21 CFR 888.3320 and 888.3330 consistent with this final order.

VII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.


List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:


2. Section 888.3320 is amended by revising paragraph (c) to read as follows:

§ 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(c) Date PMA or notice of completion of PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before May 18, 2016, for any hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component that was in commercial distribution before May 28, 1976, or that has, on or before May 18, 2016, been found to be substantially equivalent to a hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component that was in commercial distribution before May 28, 1976. Any other hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.


Leslie Kux, Associate Commissioner for Policy.

Federal Register 2016, 81, No. 32 / Thursday, February 18, 2016 / Rules and Regulations
Background

Section 6045 generally requires a broker to report gross proceeds upon the sale of a security. Section 6045 was amended by section 403 of the Act to require the reporting of adjusted basis for a covered security and whether any gain or loss upon the sale of the security is long-term or short-term. In addition, the Act added section 6045A of the Code, which requires certain information to be reported in connection with a transfer of a covered security to another broker, and section 6045B of the Code, which requires an issuer of a specified security to file a return relating to certain actions that affect the basis of the security. Section 6049 requires the reporting of interest payments (including accruals of OID treated as payments).

On November 25, 2011, the Treasury Department and the IRS published in the Federal Register the proposed regulations relating to information reporting by brokers, transferors, and issuers of securities under sections 6045, 6045A, and 6049 (the 2011 proposed reporting regulations). On March 13, 2015, the Treasury Department and the IRS published in the Federal Register the final regulations under sections 6045, 6045A, and 6049 (the 2015 proposed reporting regulations). A notice of proposed rulemaking cross-referencing the 2015 temporary reporting regulations was published in the Federal Register on March 13, 2015 (REG–143040–14 at 80 FR 13292) (the 2015 proposed reporting regulations). A correction to § 1.6045A–1T(f) was published on June 5, 2015 (TD 9713 at 80 FR 31995), delaying the effective date of § 1.6045A–1T(f) from June 30, 2015, to January 1, 2016.

Written comments were received on the 2015 proposed reporting regulations and are summarized below. No public hearing was requested or held. In general, these final regulations adopt the provisions of the 2015 proposed reporting regulations. These final regulations also remove the corresponding 2015 temporary reporting regulations.

After the publication of the 2015 final basis reporting regulations, the Treasury Department and the IRS received written comments on certain provisions of the final basis reporting regulations. In response to these comments, this document contains final regulations under section 6045 relating to the treatment of certain debt instruments as non-covered securities.

The written comments on the 2015 proposed reporting regulations and the 2015 final basis reporting regulations are available for public inspection at http://www.regulations.gov or upon request.

Explanation of Provisions

A. Constant Yield Election for Accruals of Market Discount

Under section 1276(b)(2), a customer may elect to accrue market discount on a constant yield method rather than a ratable method. The election may be made on a debt instrument by debt instrument basis and must be made for the earliest taxable year for which the customer is required to determine
accrued market discount. The election may not be revoked once it has been made. In most cases, the use of a constant yield method backloads market discount and is therefore more taxpayer favorable than the use of a ratable method.

In response to comments on the 2013 final basis reporting regulations (which required the broker to assume that the customer had not made a constant yield election), § 1.6045–1T(n)(11)(i)(B) of the 2015 temporary reporting regulations provided that for a debt instrument acquired on or after January 1, 2015, brokers are required to assume that a customer has elected to determine accrued market discount using a constant yield method unless the customer notifies the broker otherwise. A customer that does not want to use a constant yield method to determine accrued market discount must, by the end of the calendar year in which the customer acquired the debt instrument in an account with the broker, notify the broker in writing that the customer wants the broker to use the ratable method to determine accrued market discount.

No comments were received on the substantive rules in § 1.6045–1T(n)(11)(i)(B). Accordingly, the rules in the final regulations in this document are the same as the rules in § 1.6045–1T(n)(11)(i)(B). Several commenters requested permission to apply the default constant yield method to debt instruments acquired on or after January 1, 2014, which was the first date for which the broker was required to report accrued market discount under section 6045, provided that the broker had not reported accrued market discount to a customer for the 2014 calendar year using the ratable method. According to the commenters, the use of a single method to compute market discount accruals for all covered securities with market discount would simplify the calculation of accrued market discount and the reporting of this information to their customers.

The final regulations in this document permit, but do not require, a broker to apply the default constant yield method to a debt instrument acquired on or after January 1, 2014, and before January 1, 2015, provided the broker was not informed that the customer had made a section 1278(b) election (the election to include market discount in income as it accrues rather than upon a disposition or receipt of a partial principal payment), there were no principal payments on the debt instrument during the 2014 taxable year, and the broker therefore had not reported accrued market discount to the customer for the 2014 calendar year using the ratable method.

B. Transfer Statements

Under § 1.6045A–1T(e) of the 2015 temporary reporting regulations, a transferring broker is required to provide a transfer statement upon the transfer of a section 1256 option to ensure that the receiving broker has all of the information required for purposes of section 6045. The temporary regulations provided that a transfer statement is required for the transfer of a section 1256 option that occurs on or after January 1, 2016. The temporary regulations also list the data specific to section 1256 options that must be provided.

One commenter asserted that including the fair market value information on a transfer statement for a section 1256 option is unnecessary because the receiving broker can look up the information if it is needed and suggested saving space on the transfer statement by eliminating this data item. After considering the suggestion, the Treasury Department and IRS decline to adopt this suggestion. Providing fair market value information on a transfer statement will help ensure that the receiving broker is reporting an amount of realized but unrecognized gain or loss from the prior year that is consistent with the amount reported in the prior year by the transferring broker, which will minimize the possibility of double counting or omission of gain or loss.

No other comments were received on § 1.6045A–1T of the 2015 temporary reporting regulations. The rules in the final regulations in this document are substantively the same as the rules in the 2015 temporary regulations. However, the rules in § 1.6045A–1T(e) are in § 1.6045A–1(b)(4)(iv) of the final regulations in this document and the rules in § 1.6045A–1T(f) are in § 1.6045A–1(b)(3)(x) of the final regulations in this document.

C. Reporting of OID on a Tax-Exempt Obligation

To coordinate the reporting of OID under section 6049 with the reporting of basis for tax-exempt obligations under section 6045, § 1.6049–10T of the 2015 temporary reporting regulations provides that a payor must report under section 6049 the daily portions of OID on a tax-exempt obligation. The daily portions of OID are determined as if section 1272 and § 1.1272–1 applied to a tax-exempt obligation. A payor must determine whether a tax-exempt obligation was issued with OID and the amount that accrues for each relevant period. In addition, OID on a tax-exempt obligation is determined without regard to the de minimis rule in section 1273(a)(3) and § 1.1273–1(d). Because the temporary regulations require the reporting of OID, payors also must report amortized acquisition premium (which offsets OID) on a tax-exempt obligation. A broker may report either a gross amount for both OID and amortized acquisition premium, or a net amount of OID that reflects the offset of the OID by the amount of amortized acquisition premium allocable to the OID. Section 1.6049–10T of the 2015 temporary reporting regulations applies to a tax-exempt obligation acquired on or after January 1, 2017.

No comments were received on the substantive rules in § 1.6049–10T. Accordingly, the rules in the final regulations in this document are the same as the rules in § 1.6049–10T.

However, several commenters requested that, for taxable years beginning after December 31, 2016, a broker be permitted to report on Form 1099–OID the OID and acquisition premium on a tax-exempt obligation that is a covered security acquired before January 1, 2017. According to the commenters, customers might be confused because of the difference between the date that a tax-exempt obligation generally became a covered security (that is, an obligation acquired on or after January 1, 2014), and the date after which a tax-exempt obligation that is a covered security becomes subject to mandatory reporting of OID and acquisition premium (that is, an obligation acquired on or after January 1, 2017). Because a broker is required to track basis for a tax-exempt obligation that is a covered security for purposes of section 6045, the broker is responsible for calculating OID on a tax-exempt obligation acquired on or after January 1, 2014, even if the broker has no obligation to report the obligation’s OID to the customer for purposes of section 6049. To simplify the reporting of OID and acquisition premium and to minimize any customer confusion, the commenters requested that the final regulations permit a broker to report OID and acquisition discount on all tax-exempt bonds that are covered securities.

After considering the requests, for taxable years beginning after December 31, 2016, the final regulations in this document permit, but do not require, a broker to report OID and acquisition discount for a tax-exempt obligation that is a covered security acquired before January 1, 2017.
D. Treatment of Certain Debt Instruments Subject to January 1, 2016, Reporting

Under § 1.6045–1(n)(3) of the 2013 final basis reporting regulations, certain debt instruments are subject to basis reporting only if the debt instrument is acquired by a customer on or after January 1, 2016. For example, § 1.6045–1(n)(3) applies to a contingent payment debt instrument, a debt instrument that is not issued by a U.S. issuer, and a debt instrument the terms of which are not reasonably available to a broker within 90 days of acquisition of the debt instrument by the customer.

Several commenters on the 2013 final basis reporting regulations requested guidance for a debt instrument the terms of which are not reasonably available to the broker. The commenters stated that they would not have the information necessary to comply with the information reporting rules for these instruments. Several commenters stated that information for a debt instrument issued by a non-U.S. issuer and for a tax-exempt obligation is particularly difficult to obtain. One commenter noted that under SEC Release 34–67908, issued on September 21, 2012 (77 FR 59427), issuers of municipal securities are required to provide certain data to the Electronic Municipal Market Access system set up by the Municipal Securities Rulemaking Board for new issuances, but there is no requirement to file similar information for issuances already outstanding as of the November 1, 2012, effective date of the release.

The Treasury Department and the IRS agree that a broker may not always be able to obtain information for a debt instrument issued by a non-U.S. issuer or for a tax-exempt obligation issued before January 1, 2014. The final regulations in this document therefore provide that a debt instrument issued by a non-U.S. issuer or a tax-exempt obligation issued before January 1, 2014, is treated as a noncovered security (and, therefore, is not subject to basis reporting under section 6045) if the terms of the debt instrument are not reasonably available to the broker within 90 days of the date the debt instrument was acquired by the customer. The Treasury Department and the IRS believe that the information necessary for section 6045 compliance should be available for other debt instruments.

Applicability Dates

The final regulations under section 6045 in this document (other than § 1.6045–1(n)(12]) apply to a debt instrument acquired on or after January 1, 2015. Section 1.6045–1(n)(12) applies to a debt instrument acquired on or after February 18, 2016. The final regulations under section 6049 in this document apply to a tax-exempt obligation that is a covered security acquired on or after January 1, 2017. The final regulations under section 6045A in this document apply to a transfer of a section 1256 option that occurs on or after January 1, 2016, and to a transfer of a debt instrument that occurs on or after January 1, 2016.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that the final regulations in this document will not have a significant economic impact on a substantial number of small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. It is anticipated that the requirements in the final regulations in this document, except in the case of the notification by a customer discussed in the next paragraph, will fall only on financial services firms with annual receipts greater than the $38.5 million threshold and, therefore, on no small entities.

Section 403(a) of the Act requires a broker to report the adjusted basis of a debt instrument that is a covered security. Although a holder of a debt instrument (customer) is permitted to make a number of elections that affect how basis is computed, a broker only is required to take into account specified elections in reporting the adjusted basis of a debt instrument, including the election under section 1276(b)(2) to determine accruals of market discount on a constant yield method. Under the 2013 final basis reporting regulations, a customer was required to notify the broker that the customer had made the section 1276(b)(2) election. However, § 1.6045–1(n)(11)(i)(B) requires a broker to take into account the election under section 1276(b)(2) in reporting a debt instrument’s adjusted basis unless the customer timely notifies the broker that the customer has not made the election. The notification must be in writing, which includes a writing in electronic format. In most cases, this election results in a more taxpayer-favorable result than the default ratable method.

It is anticipated that this collection of information in the regulations will not fall on a substantial number of small entities, especially because fewer customers will need to notify brokers about the election. Further, the regulations implement the statutory requirements for reporting adjusted basis under section 403 of the Act. Moreover, any economic impact is expected to be minimal because it should take a customer no more than seven minutes to satisfy the information-sharing requirement included in these regulations.

Section 403(c) of the Act added section 6045A, which requires applicable persons to provide a transfer statement in connection with the transfer of custody of a covered security. Section 1.6045A–1 effectuates the Act by giving the broker who receives the transfer statement the information necessary to determine and report adjusted basis and whether any gain or loss with respect to a debt instrument or section 1256 option is long-term or short-term as required by section 6045 when the security is subsequently sold. Consequently, § 1.6045A–1 does not add to the impact on small entities imposed by the statutory provisions. Instead, the regulations limit the information to be reported to only those items necessary to effectuate the statutory scheme.

The information required under § 1.6049–10 will enable the IRS to verify that a taxpayer is reporting the correct amount of tax-exempt interest each year for alternative minimum tax and other purposes. In addition, because this information is used to determine a taxpayer’s adjusted basis in a debt instrument for purposes of section 6045(g), this information is required to enable the IRS to verify that a taxpayer is reporting the correct amount of gain or loss upon the sale of a tax-exempt obligation. Any economic impact on small entities is expected to be minimal because a broker already is required to determine the accruals of OID and acquisition premium for purposes of determining and reporting a customer’s adjusted basis on Form 1099–B under section 6045. Moreover, any effect on small entities of the rules in the final regulations flows from section 6049 and section 403 of the Act.

Therefore, because the final regulations in this document will not have a significant economic impact on a substantial number of small entities, a regulatory flexibility analysis is not required.

Pursuant to section 7805(f) of the Internal Revenue Code, the proposed regulations preceding the final regulations in this document were
submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses. No comments were received.

Drafting Information

The principal author of these regulations is Pamela Lew, Office of Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

§ 1.6045–1 Returns of information of brokers and barter exchanges.

* * * * *

(n) * * * * However, see paragraph (n)(11)(i)(A) of this section for a debt instrument acquired on or after January 1, 2014.

* * * * *

(5) * * * *

(i) * * * * However, see paragraph (n)(11) of this section for the treatment of an election described in paragraph (n)(4)(iii) of this section (election to accrue market discount based on a constant yield) and an election described in paragraph (n)(4)(iv) of this section (election to treat all interest as OID).

* * * * *

(6) * * * *

(i) * * * * See paragraphs (n)(5) and (n)(11)(i)(B) of this section to determine whether the amount reported should take into account a customer election under section 1276(b)(2).

(ii) * * * * See paragraphs (n)(5) and (n)(11)(i)(B) of this section to determine whether the amount reported should take into account a customer election under section 1276(b)(2).

(7) * * * *

(iii) * * * * However, if a broker took into account a customer election under § 1.1272–3 in 2014, the broker must decrease the customer’s basis in the debt instrument by the amount of acquisition premium that is taken into account each year to reduce the amount of the original issue discount that is otherwise includible in the customer’s income for that year in accordance with §§ 1.1272–2(b)(5) and 1.1272–3.

* * * * *

(11) Additional rules for certain holder elections—(i) In general. For purposes of this section, the rules in this paragraph (n)(11) apply notwithstanding any other rule in paragraph (n) of this section.

(A) Election to treat all interest as OID. A broker must report the information required under paragraph (d) of this section without taking into account any election described in paragraph (n)(4)(iv) of this section (the election to accrue market discount based on a constant yield). However, if a customer notifies a broker in writing that the customer does not want the broker to take into account this election, the broker must report the information required under paragraph (d) of this section without taking into account this election. The customer must provide this notification to the broker by the end of the calendar year in which the customer acquired the debt instrument in an account with the broker. This paragraph (n)(11)(i)(B) applies to a debt instrument acquired on or after January 1, 2015. A broker, however, may rely on this paragraph (n)(11)(i)(B) to report accrued market discount for a debt instrument that is a covered security acquired on or after January 1, 2014, and before January 1, 2015, if the customer had not informed the broker that the customer had made a section 1278(b) election and there were no principal payments on the debt instrument during this period.

(ii) Reserved.

(12) Certain debt instruments treated as noncovered securities—(i) In general. Notwithstanding paragraph (a)(15) of this section, a debt instrument is treated as a noncovered security for purposes of this section if the terms of the debt instrument are not reasonably available to the broker within 90 days of the date the debt instrument was acquired by the customer and the debt instrument is either—

(A) A debt instrument issued by a non-U.S. issuer; or

(B) A tax-exempt obligation issued before January 1, 2014.

(ii) Effective/applicability date. Paragraph (n)(12)(i) of this section applies to a debt instrument described in paragraph (n)(12)(i)(A) or (B) of this section that is acquired on or after February 18, 2016. However, a broker may rely on paragraph (n)(12)(i) of this section for a debt instrument described in paragraph (n)(12)(i)(A) or (B) of this section acquired before February 18, 2016.

* * * * *

§ 1.6045–1T Returns of information of brokers and barter exchanges (temporary).

* * * * *

(h) through (p) [Reserved]. For further guidance, see § 1.6045–1(h) through (p).

* * * * *
Par. 4. Section 1.6045A–1 is amended by:
1. Removing “and” at the end of paragraph (b)(3)(viii), removing the period at the end of paragraph (b)(3)(ix) and adding “and;” in its place, and adding paragraph (b)(3)(x).
2. Removing “and” at the end of paragraph (b)(4)(ii), removing the period at the end of paragraph (b)(4)(iii) and adding “and;” in its place, and adding paragraph (b)(4)(iv).
3. Removing paragraphs (e) and (f).

The additions read as follows:

§ 1.6045A–1 Statements of information required in connection with transfers of securities.

* * * * *
(b) * * *
(3) * * *
(x) For a transfer that occurs on or after January 1, 2016, the last date on or before the transfer date that the transferor made an adjustment for a particular item (for example, the last date on or before the transfer date that bond premium was amortized). A broker, however, may rely on this paragraph (b)(3)(x) for a transfer of a covered security that occurs on or after June 30, 2015, and before January 1, 2016.

(4) * * *
(iv) For a transfer of an option described in § 1.6045–1(m)(3) (section 1256 option) that occurs on or after January 1, 2016, the original basis of the option and the fair market value of the option as of the end of the prior calendar year.

* * * * *
§ 1.6045A–1T [Removed]

Par. 5. Section 1.6045A–1T is removed.

Par. 6. Section 1.6049–10 is added to read as follows:

§ 1.6049–10 Reporting of original issue discount on a tax-exempt obligation.

(a) In general. For purposes of section 6049, a payor (as defined in § 1.6049–4(a)(2)) of original issue discount (OID) on a tax-exempt obligation (as defined in section 1288(b)(2)) is required to report the daily portions of OID on the obligation as if the daily portions of OID that accrued during a calendar year were paid to the holder (or holders) of the obligation in the calendar year. The amount of the daily portions of OID that accrues during a calendar year is determined as if section 1272 and § 1.1272–1 applied to a tax-exempt obligation. Notwithstanding any other rule in section 6049 and the regulations thereunder, a payor must determine whether a tax-exempt obligation was issued with OID and the amount of OID that accrues for each relevant period. As prescribed by section 1288(b)(1), OID on a tax-exempt obligation is determined without regard to the de minimis rules in section 1273(a)(3) and § 1.1273–1(d).

(b) Acquisition premium. A payor is required to report acquisition premium amortization on a tax-exempt obligation in accordance with the rules in § 1.6049–9(c) as if section 1272 applied to a tax-exempt obligation. See paragraph (a) of this section to determine the amount of OID allocable to an accrual period.

(c) Effective/applicability date. This section applies to a tax-exempt obligation that is a covered security (within the meaning of § 1.6045–1(a)(15) and (n)(12)) acquired on or after January 1, 2017. For a taxable year beginning after December 31, 2016, a broker, however, may rely on this section to report OID and acquisition premium for a tax-exempt obligation that is a covered security acquired before January 1, 2017.

§ 1.6049–10T [Removed]

Par. 7. Section 1.6049–10T is removed.

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

Approved: January 13, 2016.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–03429 Filed 2–17–16; 8:45 am]