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Audit and Enterprise Risk Services

Accounting for the Branded Pharmaceutical Drug Annual Fee

Effect of the Final IRS Regulations Issued in July 2014

Financial Reporting Alert 14-2
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Background

ASU 2010-27[1] (codified in ASC 720-50[2]) provides guidance on accounting and reporting related to the branded pharmaceutical drug (BPD) annual fee pursuant to the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. ASC 720-50-25-1 states, in part, the following (emphasis added):

> The liability related to the annual fee described in paragraphs 720-50-05-1 through 05-4 shall be estimated and recorded in full upon the **first qualifying sale** for pharmaceutical manufacturers or once the entity provides qualifying health insurance for health insurers **in the applicable calendar year in which the fee is payable** with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable.

Under ASC 720-50-25-1, a calendar-year entity would recognize the estimated BPD fee obligation (payable to the U.S. Treasury in September 2014) and corresponding deferred cost upon the first qualifying sale in 2014. Accordingly, the trigger event that would have obligated an entity to pay its portion of the BPD fee in any given calendar year under ASC 720-50-25-1 would have been the "first qualifying sale" in that calendar year.

Effect of IRS Regulations

On July 28, 2014, the IRS issued **final regulations** related to the BPD fee that contain a new term, “covered entity status” (see definition and related example **below**). The final regulations indicate that an entity’s obligation to pay its portion of the BPD fee in any given calendar year is not triggered by the first qualifying sale in that calendar year but instead by the qualifying sales in the previous year. As a result, entities have questioned whether to continue applying the recognition guidance in ASC 720-50 in accounting for the BPD fee.

On the basis of a discussion with the SEC staff, we understand that the SEC staff has discussed the regulations with the U.S. Treasury and, on the basis of those discussions, it is the understanding of the SEC staff that no changes are expected to be made to the final IRS regulations. Accordingly, for financial reporting periods that include the July 28, 2014, effective date of the final IRS regulations, the accounting for the BPD fee should be based on the final IRS regulations, which require the following:

- The write-off to expense of any remaining asset previously recorded for the BPD fee under ASC 720-50.
- A catch-up adjustment to expense to recognize the BPD fee payable based on 2014 year-to-date qualifying sales.
- The recognition of expense for the BPD fee in remaining periods in 2014 and beyond as qualifying sales

occur.

The SEC staff noted that it would not object to the above recognition accounting for the BPD fee. Furthermore, the staff indicated that it would not object if an entity continued to apply the income statement presentation guidance in ASC 720-50-45-1 for the BPD fee, which requires the fee to be presented as an operating expense. For financial reporting periods that include the effective date of the final IRS regulations (September 30, 2014, for a calendar-year entity), entities should consider disclosing information about the change in recognition of the BPD fee resulting from the final IRS regulations, the impact of the catch-up adjustment recorded in the period, and how the BPD fee will be accounted for prospectively.

Definition of Covered Entity Status

IRS regulations (26 CFR § 51.2(e)(5)) define "covered entity status" as follows:

> *Covered entity status*—(i) *Rule*. An entity's status as a covered entity begins in the first fee year in which the entity has branded prescription drug sales and continues each subsequent fee year until there are no remaining branded prescription drug sales for that entity to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e).
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> (ii) *Example*. The following example illustrates the rule of paragraph (e)(5)(i) of this section:
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> (A) *Facts*. Entity A is a manufacturer with gross receipts of more than $5 million from branded prescription drugs sales in 2011. Entity A does not have any gross receipts from branded prescription drug sales before or after 2011.
>
> (B) *Analysis*. Entity A is a covered entity beginning in 2011 because it had gross receipts from branded prescription drug sales in 2011. For the 2011 fee year, Entity A does not owe a fee because the 2011 fee is based on sales data from the 2009 sales year. For the 2012 fee year, Entity A does not owe a fee because the 2012 fee is based on sales data from the 2010 sales year. Entity A continues to be a covered entity for the 2012 fee year because its branded prescription drug sales from the 2011 sales year have not yet been taken into account as described in §51.5(c) and used to calculate the adjustment amount described in §51.5(e). For the 2013 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales from the 2011 sales year are taken into account as described in §51.5(c) for purposes of computing the 2013 fee. For the 2013 fee year, Entity A is also liable for the adjustment amount described in §51.5(e) for the difference between its 2012 fee computed using sales data from the 2010 sales year, which is $0, and what the 2012 fee would have been using sales data from the 2011 sales year. For the 2014 fee year, Entity A continues to be a covered entity because a portion of its branded prescription drug sales for the 2011 sales year are used to calculate the adjustment amount described in §51.5(e). Therefore, for the 2014 fee year Entity A will receive an adjustment amount for the difference between its 2013 fee computed using sales data from the 2011 sales year, and what the 2013 fee would have been using sales data from the 2012 sales year, which is $0. After the 2014 fee year, there are no remaining branded prescription drug sales to be taken into account as described in §51.5(c) or used to calculate the adjustment amount described in §51.5(e) for Entity A. Accordingly, Entity A is not a covered entity after the 2014 fee year.

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1 FASB Accounting Standards Update No. 2010-27, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers* — a consensus of the FASB Emerging Issues Task Force.

2 For titles of *FASB Accounting Standards Codification* (ASC) references, see Deloitte's **"Titles of Topics and Subtopics in the *FASB Accounting Standards Codification*."**

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