

## Life Sciences Spotlight

# Accounting for the Branded Prescription Drug Annual Fee

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## The Bottom Line

The total annual fee for 2011 is \$2.5 billion and has been allocated to companies on the basis of their proportionate share of qualifying governmental sales.

- Effective this year, manufacturers and importers of branded pharmaceutical drugs are required to pay an annual fee to the government on the basis of their proportional share of qualifying governmental sales. The IRS has recently issued temporary regulations covering the administration of the annual fee.
- When imposed, the annual fee due in the current calendar year is initially measured on the basis of qualifying sales from two years prior; the annual fee due in the following calendar year will include a true-up of the previous year's fee (i.e., to adjust such fee for qualifying sales in the first, rather than second, year preceding that year).
- Under the provisional IRS regulations, the 2011 annual fee due is measured by the IRS on the basis of qualifying sales for 2009. Similarly, the 2012 annual fee due will be measured on the basis of qualifying sales for 2010; however, the amount due in 2012 will also be adjusted for the IRS true-up of the 2011 annual fee on the basis of qualifying sales for 2010 instead of 2009.
- Questions have arisen regarding the accounting for the IRS true-up of the annual fee and whether it should be recognized in the current calendar year (on an estimated basis) or in the following calendar year (when it is settled).
- Our interpretation of the IRS temporary regulations leads us to believe that a company should accrue for its best estimate of the annual fee due for the current year. This best estimate should include the provisional calculation under the IRS regulations plus the estimated IRS true-up adjustment to occur in the following year; accordingly, the aggregate 2011 accrual would be based on the best information available regarding the proportionate share of qualifying sales for 2010.

# Beyond the Bottom Line

This *Life Sciences Spotlight* highlights certain accounting considerations associated with the branded prescription drug annual fee that was implemented this year.

## Background

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act were signed into law (collectively, the “legislation”). Beginning in calendar year 2011, the legislation imposes an annual fee on manufacturers and importers of branded pharmaceuticals. The total annual fee for 2011 is \$2.5 billion and has been allocated to companies on the basis of their proportionate share of qualifying governmental sales.

In November 2010, the IRS issued [Notice 2010-71](#), which provides further details on the implementation of the annual fee imposed by the legislation. Specifically, Notice 2010-71 states that qualifying sales in the second calendar year preceding the fee year, rather than the immediately preceding calendar year, would be used for the calculation of the annual fee due in that year. The IRS acknowledged that certain governmental programs did not have complete data for the immediately preceding year within the time frame necessary to administer the annual fee. Accordingly, the subsequent year’s fee would include a true-up adjustment to the prior year’s fee, which would be remeasured on the basis of the immediately preceding calendar year.

In August 2011, the IRS published [temporary regulations](#) that provided guidance on how it would calculate the annual fee. The IRS reiterated its position that the annual fee would be based on the branded prescription drug sales data provided by the governmental agencies for the second calendar year preceding the fee year and that the annual fee due in every year after 2011 would include an adjustment to the prior year’s fee.

## Accounting Considerations

In December 2010, the FASB issued ASU 2010-27, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers*, which amended ASC 720, *Other Expenses*, to provide guidance on accounting for the annual fee paid in accordance with the legislation. As a result of ASU 2010-27, the liability related to the annual fee should be estimated and recorded in full upon the first qualifying sale (upon which the manufacturer became legally obligated to pay the fee); a corresponding deferred cost is recognized that is amortized to expense under a straight-line method of allocation unless another method better allocates the fee over the year. The annual fee should be presented in the income statement as an operating expense.

However, questions have arisen regarding the accounting for the IRS true-up of the annual fee and whether it should be recognized in the current calendar year (on an estimated basis) or in the following calendar year (when it is settled). We believe that the annual fee accrual should be measured on qualifying sales in the immediately preceding year, which would take into account the amount actually paid in the current year and the associated IRS true-up adjustment expected in the following year. This is consistent with the notion that the liability to pay the annual fee is incurred in connection with the first qualifying sale of the year. Furthermore, our understanding of the legislation’s requirements is that the government would expect to recover a fixed amount for each year (e.g., \$2.5 billion for 2011) and that the IRS true-up adjustment in the subsequent year would be expected to take place regardless of whether there are qualifying sales for that subsequent year.

Estimating the annual fee that pertains to the current calendar year may prove challenging. A company must consider its own qualifying sales relative to the overall marketplace. And measuring qualifying sales, for example, may require consideration of product launches, products that have lost patent exclusivity, product recalls, and certain exclusion provisions contained in the temporary regulations.

Questions have arisen regarding the accounting for the IRS true-up of the annual fee.

## Thinking Ahead

Companies have the opportunity to review and respond to the IRS temporary regulations through November 16, 2011. In addition, companies should examine the provisions of the final regulations to ensure that any resulting changes in measuring and administering the annual fee are reflected in the current year accrual.

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### Other Deloitte Resources

- [\*Tax News and Views\*, August 19, 2011.](#)

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