Change in timing for recording the Annual Pharmaceutical Fee

Background
In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). The legislation imposed an annual fee on companies in the pharmaceutical manufacturing sector for each calendar year beginning in 2011. The fee ranges from $2.5 billion to $4.1 billion and is payable no later than September 30 of the applicable calendar year. The fee is non-deductible and is allocated across the industry based on the company's relative market share of applicable sales to government programs.

The 2011 annual fee was $2.5 billion and is scheduled to grow to $4.1 billion before declining to $2.8 billion in 2019. The total annual fee is allocated among all manufacturers and importers using the ratio of (i) the covered entity’s branded prescription drug (“BPD”) sales, as defined, during the sales year to (ii) the aggregate BPD sales, as defined, for all covered entities during the same year. Branded prescription drug sales means sales of any BPD to any specified government program or pursuant to coverage under any government program (specifically, Medicare Part D, Medicare Part B, Medicaid, Department of Veteran Affairs, Department of Defense and TRICARE). The sales included in the calculation are reduced for covered entities with BPD drug sales less than $400 million on a sliding scale and eliminated entirely for covered entities with BPD sales less than $5 million. Additionally, orphan drugs sales are excluded from the calculation.

At the time this legislation was enacted, the accounting for the annual fees was discussed with the SEC and ultimately the Emerging Issues Task Force (EITF). The issues addressed in 2010 included (1) the appropriate year for the recognition of the initial fee, (2) the income statement classification of the fee, and (3) how to recognize the expense in the year the fee is owed. With regard to the timing of recognition, a conclusion was reached that the annual fee should be recognized in the calendar year in which the entity becomes obligated to pay the fee (which was determined to be the year subsequent to when the sales were incurred). Additionally, the EITF concluded that the fee should be accounted for as an operating expense and spread ratably over the year in which it comes due. That guidance was provided in Accounting Standards Update 2010-27.
**Current Issue**

On July 28, 2014, the IRS issued final regulations that provide guidance on the annual fee imposed by the PPACA. The regulations include an example calculation of the pharmaceutical fee and other references, which differ in some respects from how companies believed the fee would be determined based on the colloquy from Senator Max Baucus from 2010 and temporary regulations issued in August 2011. The final IRS regulations suggest that a company is liable for the fee based on sales in the current year, instead of the liability only being due upon the first qualifying sale of the following fee year. As a result of this change, we believe the fee should be recorded in the period in which the sales occur.

Pharmaceutical manufacturers that have recorded expense in 2014 only for the fees associated with 2013 sales will need to record a catch-up adjustment in the quarter that includes July 28, 2014 (Q3 2014 for a calendar year-end company). The adjustment should (i) recognize a liability for the fee payable based on 2014 sales to date and (ii) eliminate any remaining prepaid asset recorded under the previous accounting. Additional expense will need to be recorded as additional sales occur in 2014.

This matter was recently discussed with the staff of the SEC, who did not object to the view expressed above.

**Other Considerations**

Because the annual fee for 2014 (and any future year) will be determined based on a company’s market share in that year, the fee will need to be estimated for purposes of making (i) the catch-up adjustment in Q3, and (ii) the ongoing accrual. In this regard, it is important to consider whether there could be significant changes to a company’s market share from one year to the next. This might be the case, for example, if the company has a branded product coming off patent which would reduce their market share. Alternatively, if a competitor has a “blockbuster” drug coming off patent, a company might project an increase in market share.

Other considerations regarding the fee include the tax implications. As the annual fee is not tax deductible, recording an additional twelve months of expense could have a significant impact on a company’s annual effective income tax rate. Consideration should be given to the impact of the pre-tax charge to the interim tax provision for Q3 2014. ASC 740-270-20 states that the annual effective tax rate approach should be used for recording the tax effect of ordinary income. Significant items that are considered unusual or infrequent are excluded from the annual effective rate and instead recorded in the quarter in which they occur. The annual pharmaceutical fee is typically included in the annual effective tax rate as it represents a recurring item to the pharmaceutical industry. However, companies should consider whether the catch-up adjustment should be treated as a discrete item for purposes of reporting interim tax expense.

Finally, companies should consider additional disclosures to help investors understand the unusual nature of the catch-up adjustment in 2014, as well as the change to the trigger for recording the expense prospectively. Such disclosures might also address the impact of the catch-up adjustment on the company’s effective tax rate.

**Questions**

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