US Healthcare Reform: Accounting issues
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Background

On 23 March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA) that was passed by the Senate in December 2009 and by the House of Representatives in March 2010. In addition, the Senate and House of Representatives passed the Health Care and Education Reconciliation Act (HCERA), which includes a number of changes to PPACA, in late March which was signed into law by President Obama on 30 March 2010.

There are a number of provisions in the new health care law that will impact the accounting for many companies. Among those provisions are the following:

- A new annual fee on pharmaceutical manufacturers
- A new excise tax on medical device manufacturers
- Revenue and channel considerations:
  - Changes to the Medicaid rebate rate
  - Expansion of the 340(b) Public Health Service (PHS) programme
  - Changes for Medicare and Medicaid recipients who are over 65 and indigent
  - Medicare coverage gap (‘doughnut hole’)
- Changes to the Retiree Drug Subsidy (RDS)

As this is significant new legislation, the discussion below is based on our current understanding of the legislation and the views below are subject to change based on new information or interpretation of the legislation.

Analysis of accounting issues

IFRS analysis

1. Annual fee on pharmaceutical manufacturers

The legislation imposes an annual fee on the pharmaceutical manufacturing sector for each calendar year beginning after 2010. The fee ranges from $2.5 billion to $4.1 billion and is payable no later than 30 September of the applicable calendar year. This is a non-deductible fee which will be allocated across the industry based on relative market share.

The calculation will be based on a covered entity’s branded prescription drug sales for the preceding year as a percentage of the industry’s branded prescription drug sales for the preceding year. Branded prescription drug sales means sales of any branded prescription drugs to any specified government programme or pursuant to coverage under any government programme (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 branded prescription drug sales less than $400 million on a sliding scale and eliminated entirely for covered entities with branded prescription drug sales less than $5 million. Additionally, orphan drugs sales are excluded from this calculation.

The annual fee payable in a given calendar year is determined by reference to sales in the preceding calendar year. As such, the question arises as to whether the annual fee should be accrued and recognised in the period the relevant sales on which the fee is determined are recognised (e.g. record a liability in 2010 for the amount payable in 2011) or whether the annual fee is more akin to a fee assessed for the annual right to participate in the government programmes that should be recognised in the period in which it is due (e.g. record a liability in 2011 even though the calculation is based on 2010 sales).
When should the annual fee on pharmaceutical manufacturers be recognised?

We believe that the annual fee should be recognised in the calendar year in which the entity becomes obliged to pay the fee (i.e. the payment becomes unavoidable) based on the payment provisions of the law. This is based on the principles articulated in IFRIC 6, ‘Liabilities arising from participating in a specific market – waste electrical and electronic equipment’. This interprets IAS 37, ‘Provisions, contingent liabilities and contingent assets’ in the context of the disposal of electrical equipment in the European Union. The IFRIC concluded that the “obligation...is linked to participation in the market during the measurement period, rather than to production or sale of items...There is no obligation unless and until a market share exists during the measurement period”. [IFRIC 6, para 9]. In the context of the annual fee on pharmaceutical manufacturers, the ‘measurement period’ is the period when sales are generated that results in an entity being a ‘covered entity’. A liability first arises only when sales are made in calendar year 2011, and that liability is calculated based on market share during 2010.

We do not believe that it is appropriate to record the fee in the period that the sales are made which then determine the market share (i.e. 2010 in the example above) under IFRS.

Our view is that the charge should be recognised at the point when the entity has exceeded the de minimis level of relevant sales in the calendar year when the obligation arises. After this point an unavoidable obligation arises for the entire amount due to the government, based on the prior year’s sales.

Although the entire amount becomes due after the de minimis level of relevant sales is made, the fee is intended to be an annual one and in substance allows an entity to participate and sell their products to government programmes in the year that the annual fee is paid. If the fee is not paid, an entity loses the right to participate in selling to US government programmes. The liability recognised therefore gives rise to an asset, which may be characterised as the implicit right to operate for the year or as a prepaid rebate. An asset is “...a resource controlled by the entity as a result of past events and from which future economic benefits are expected to flow to the entity”. [Framework para 49(a)]. Therefore, the fee may be capitalised and amortised over the relevant year.

How should the annual fee on pharmaceutical manufacturers be classified in the income statement?

Our view is that the charge should be classified as a reduction in revenue. The annual fee is calculated based on sales to government programmes. If an entity makes no sales to government programmes in the relevant period or, importantly, makes sales to non-government programmes, the fee is not payable. It is, therefore, directly linked to one particular customer (the US government). The fee is amortised as a right to do business in US government programmes or as a reduction in the prepaid rebate and should be accounted for as a reduction in revenue from those programmes.

2. Excise tax on medical device manufacturers

The new health care law imposes an excise tax of 2.3% on the sale of any taxable medical device by the medical device manufacturer. The excise tax will apply to sales after 31 December 2012. The legislation states that this tax applies to all devices which are intended for humans except for certain items such as contact lenses, eyeglasses and hearing aids. Additionally, the Secretary can exclude any other medical device determined to be of a type which is generally purchased by the public at retail for individual use. Medical device manufacturers would need to begin accounting for this fee for all sales beginning 1 January 2013 by direct analogy with the fee on pharmaceutical manufacturers.

How should the excise tax on medical device manufacturers be classified in the income statement?

There is no specific IFRS dealing with excise taxes. The key is to determine whether the medical device manufacturer is acting as agent for the government (collecting sales taxes on behalf of customers) or is acting as principal (and the tax is a cost charged to the medical devices manufacturer).

Indicators that the medical devices manufacturer is acting as principal (and the tax is an expense) include but are not limited to:

- Risks and rewards of the transaction – the entity holds the inventory and credit risk and the entity will not be refunded even if the inventory is not sold or receivables are not collected.
The medical devices manufacturer only pays if products are sold. However, amounts are payable whether or not a debtor fails to pay. The debtor may be the US government or it may be insurance companies or individuals. This indicates that the medical devices manufacturer is acting as principal.

- Ability to choose the selling price – the entity has no legal or constructive obligation to change prices in order to reflect excise taxes. The entity bears the taxes and makes the decision whether to pass the tax on to the customer.

The medical devices manufacturer does not have an obligation to pass the charge on to the customer. This indicates that it is acting as principal.

- Basis of calculation – the tax is based on the number of units or on the physical quantity (for example number of cigarettes, or alcoholic content) produced by the entity.

The tax is based on the sales value, which indicates that it is a sales tax and should be presented net of revenue (medical devices manufacturer acting as agent).

- Point of payment – the entity must pay tax to the government when the unit is produced or relatively close to that date.

The tax is payable following sales rather than production, indicating that the medical devices entity is acting as agent and the tax should be presented net within revenue.

The above indicators are mixed. However, the stronger indicators are the medical devices manufacturer having to pay the excise tax—even if its customer does not pay—and the manufacturer not being required to pass the charge on to customers. Our preferred view is that the excise tax is presented as an expense.

3. Revenue and channel considerations

The legislation introduces several changes that will impact the estimates a pharmaceutical company will make regarding the ultimate amount it expects to receive for its sales. These changes include:

- Increases to the Medicaid prescription drug rebate effective as of 1 January 2010.
  - Single source and innovator multiple source outpatient prescription drugs (branded) from 15.1% to 23.1%.
  - Clotting factors and other drugs specifically approved by the FDA exclusively for paediatric indications to 17.1%.
  - Multi-source non innovator (generics) drugs from 11% to 13%.

- Expansion of the 340(b) PHS programme to include certain children’s hospitals, cancer hospitals, critical access and sole community hospitals and rural centres. This change is effective as of 1 January 2010.

- Extension of Medicaid rebates to drugs supplied to enrollees of Medicaid managed care organisations (MCOs). This change is effective 23 March 2010.

- Changes to the calculation of Medicaid rebates for new formulations of existing drugs. This change is effective 1 January 2010.

- Pharmaceutical drug manufacturers will be required to fund 50% of the Medicare coverage gap starting on 1 January 2011.

How will the legislative changes impact pharmaceutical companies?

The legislation will impact the ultimate amount that will be received by each company for each sale to the government. Several of the changes noted above will impact companies as early as the quarter ended 31 March 2010.

The increased Medicaid prescription drug rebate applies to all products sold to Medicaid recipients starting on 1 January 2010. As such, companies will need to record the impact that the increased rebate rate has on products that have been previously sold under these programmes during the quarter ended 31 March 2010. In addition, companies will need to record the
impact for any sales that reside in the wholesale or retail channels and will be utilised by Medicaid recipients.

The increase in the 340(b) PHS programme is also effective as of 1 January 2010. However, companies are not able to give discounts to a hospital unless they are included on the list of eligible hospitals (on the Health Resources and Services Administration (HRSA) website). It is unclear when the entities that will be added to the 340(b) programmes will be added to the HRSA list. In addition, there is no formal ‘mechanism’ in place to provide these discounts. However, as this provision is in the enacted law, we believe that companies should record the estimated impact of this legislative change during the quarter ended 31 March 2010 assuming retroactive effect to 1 January 2010. We also believe that companies will need to reassess their original estimates when the list of eligible companies and mechanics of the programme are known.

The change to MCOs relates to states that have a portion of their Medicaid lives covered by MCOs, for which the states would pay a capitated (fixed) rate. Prior to the Patient Protection and Affordable Care Act (PPACA), these MCO plans were only entitled to a commercial discount to the extent they had a contract with manufacturers. Under the PPACA, the statutory Medicaid rebate is now applicable under these plans. Companies will need to estimate utilisation for enrollees who are covered by MCO plans for the quarter ended 31 March 2010. Medicaid rebates, including Consumer Price Index (CPI) penalties, may be higher than existing contractual rebates to which managed Medicaid plans had been previously entitled. The statute as written was unclear as to the start date for this change. On 1 April 2010, in an email to “The Pink Sheet” DAILY, Centers for Medicare & Medicaid Services (CMS) stated that the effective date of the MCO rebate change is 23 March 2010. From a practical standpoint, for the first quarter of 2010, this will mean that most companies will need to estimate the impact resulting from the above described MCO change on their wholesale and retail pipeline assumptions in their accrual models.

The change related to the new formulation of existing drugs, deals with the Consumer Price Index for all Urban Consumers (CPI-U) penalty (“additional” Medicaid rebate) for line extensions (for example, extended release versions of existing products). The PPACA adds an additional calculation which may increase the amount of additional rebate which is added to the base Medicaid rebate of the new formulation. Careful consideration should be given to determine whether or not a product would be considered a new formulation, for which this change would be applicable, or a new product. Companies should consider whether discussion with legal counsel is necessary. The change is effective retroactive to 1 January 2010.

The changes related to the Medicare coverage gap do not begin to take effect until 2011. There are many operational and accounting challenges that drug manufacturers will need to work through related to this change. The challenges include how the Medicare coverage gap programme will operate and when companies will need to begin to account for these changes. We believe that companies will need to possibly begin accounting for sales in the wholesale channel as early as Q4 2010 for certain of these changes. We would expect to issue more guidance related to accounting for the Medicare coverage gap as the details of the programme become known.

4. Changes to the Retiree Drug Subsidy

The legislation contains a provision that changes the tax treatment of the Retiree Drug Subsidy (RDS). The change requires that the amount of the subsidy received be offset against the employer’s deduction for health care expenses, whereas, previously, the subsidy was ignored for tax purposes. The change does not affect the taxation of the subsidy itself but reduces the employer’s deduction for the costs of healthcare for retirees by the amount of the subsidy received. This change is effective beginning on 1 January 2013.

How should the change in tax treatment of the RDS be accounted for?

Post-employment healthcare plans are accounted for in the same way as defined benefit pension plans under IAS 19, ‘Employee benefits’. A charge is recorded in the income statement for the current service cost, interest cost, past service cost and the effect of any curtailments or settlements. Depending on an entity’s accounting policy, actuarial gains and losses may either have been:
• Recognised immediately in the income statement.
• Recognised immediately in other comprehensive income.
• Partially recognised in other comprehensive income under the ‘corridor’ method.

The temporary difference on which deferred tax is recognised is the difference between the medical cost liability and its tax base (being the carrying amount less amounts deductible in the future).

The deferred tax rules in IFRS require the effect of a change in tax laws be recorded in the income statement except to the extent that it relates to items that were previously recognised outside profit or loss. [IAS 12, para 60]. This means that an entity will have to determine how the amounts included in the temporary difference arose. The effect of the change in tax law should then be appropriately apportioned between the 2010 income statement and statement of other comprehensive income, as a current period adjustment.

The backwards-tracing for the change in the tax law should be consistent with the approach used for allocating tax deductions. The deferred tax asset, which is impacted by the tax law change, represents the tax on amounts against which tax deductions have not yet been allocated. To the extent that amounts in the performance statements are covered by deductions received on contributions, no deferred tax arises. The deferred tax arises on any excess amounts in the performance statements (that is, in the income statement and statement of other comprehensive income, where presented separately) and the backwards-tracing should be carried out on that basis.

The fact that a medical costs liability recognised on transition to IFRS was charged to equity does not necessarily mean that subsequent changes in the related deferred tax asset will also be recognised in equity. Instead, it is necessary to determine where the items on which the original deferred tax arose would have been recognised if IFRS had been applied in the prior periods.

US GAAP analysis

1. Annual fee on pharmaceutical manufacturers

When should the annual fee on pharmaceutical manufacturers be recognised?

We believe the annual fee should be recognised over the calendar year in which the entity becomes obligated to pay the fee (payment becomes unavoidable) based on the payment provisions of the law.

The basis for this conclusion is that no liability as defined by CON 6 exists prior to an entity generating sales into a government programme that cause them to be a “covered entity”, and therefore subject to the fee, in a particular year. For example, it is the sale of branded prescription drugs to a specified government programme in 2011 that causes an entity to be subject to the fee in 2011. The sales in 2010 are solely used to calculate the fee; they do not obligate the entity to pay the fee. This is further supported by the provision in the Health Care and Education Reconciliation Act which states that the section of the bill relating to the fee on the pharmaceutical industry only applies to calendar years beginning after 31 December 2010. Additionally, Senator Baucus read a statement into the congressional record in late March that supported the view that an entity would not owe the fee if it had no participation in the relevant government programmes even if the entity had qualifying sales in the preceding year.

This conclusion reflects what many believe was the intent of the legislation. That is, to require a fee to be paid in the year in which a company has sales under the relevant government programmes. The amount represents an annual cost of doing business for the industry. The use of the prior year sales to allocate the total fee across the industry participants was to have a method to calculate market share and should not be construed to relate to the period for which the liability relates. This conclusion is based on the current interpretation of how PPACA will be implemented by Treasury. If Treasury implementation is different than current interpretations, the accounting will need to be revisited at that time.
It should be noted that this issue has been discussed with members of the Securities and Exchange Commission (SEC) staff who have indicated that they will not object to the accounting described above.

Another view that could be taken is to record the fee in the period of sales. This view is supported by guidance in Accounting Standards Code (ASC) Paragraph 605-50-25-7 (pre-codification Emerging Issues Task Force (EITF) 01-9) with the key fact being that the fee is determined by reference to sales in the preceding calendar year. Since the annual fee is linked to those sales transactions, the fee would be accrued and recognised in the period the relevant sales occur. Based on a recent discussion with the SEC, we believe a company that wishes to follow this approach may want to have further discussions with the Staff.

We believe the charge would generally be recognised over the calendar year using a straight-line attribution method. We expect further discussion (including potential EITF consideration) in regard to the balance sheet treatment of the annual fee. In particular, whether a company should accure the entire amount of the fee due at the beginning of the calendar year (i.e., when it had the first dollar of sales) and record an offsetting deferred charge which it then would amortise throughout the year.

How should the annual fee on pharmaceutical manufacturers be classified in the income statement?

Pharmaceutical companies have a history of dealing with similar fees or excise taxes in Europe. These fees and excise taxes that are based on sales to the governmental entities have typically been accounted for as a reduction of revenues based on the income statement classification guidance in ASC 605-50, Customer Payments and Incentives, (formerly EITF 01-9). Under ASC 605-50-45-2 (formerly Issue 1 in EITF 01-9), cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor’s product or service unless certain conditions are met to overcome the presumption. As such, the vendor would classify the cash consideration given as a reduction of revenue when recognised in the income statement.

The annual fee for the pharmaceutical manufacturer is calculated based on its share of sales to qualifying governmental programmes but, unlike other taxes and rebates, this fee is not tax deductible.

Given the annual fee for the pharmaceutical manufacturer is allocated based on sales to governmental programmes, and there is no identifiable benefit with a fair value that can be reasonably estimated associated with the payment, one view is to record such payments as a reduction of revenue based on ASC 605-50-45-2.

Another view is that the annual fee represents an annual cost of doing business with the government. In fact, the legislation specifically states that the annual fee is not tax deductible, which is similar to other excise taxes. Therefore, a view can be taken that this cost should be recorded as an operating cost.

In recent discussion with the SEC, the staff indicated that there are reasonable arguments that support both views and barring future standard setting, they would not object to a policy election consistently applied for similar fees with appropriate disclosure. This accounting policy election provides companies that have sales of both pharmaceuticals and medical devices flexibility to report these costs in a manner that would provide consistency in financial reporting. In addition, a topic has now been added to the EITF agenda that will deal with the classification of these payments in the income statement and some related questions.

2. Excise tax on medical device manufacturers

How should the excise tax on medical device manufacturers be classified in the income statement?

The excise tax on medical device manufacturers is based on individual product sales to all customers. We believe that companies should consider the guidance in ASC 605-45, Principal Agent Considerations, (formerly EITF 06-03) when determining the classification of this excise tax in the income statement. This guidance states that the presentation of taxes can either be on a gross basis (i.e., included in revenue and costs) or a net basis (i.e., excluded from revenues). The guidance also states that this is an accounting policy election that should be consistently applied and disclosed.
3. Revenue and channel considerations
How will the legislative changes impact pharmaceutical companies?

The impact on pharmaceutical companies will be the same under US GAAP and IFRS.

4. Changes to the Retiree Drug Subsidy
How should the change in tax treatment of the RDS be accounted for?

As a result of the legislative change, the deductible temporary difference and any related deferred tax asset on the employer's balance sheet associated with the benefit plan will need to be reduced. Under ASC 740, the impact of a change in tax law should be immediately recognised in continuing operations in the income statement for the period that includes the enactment date. This is true regardless of the effective date of the change in the tax law, which in this case is for tax years beginning after 31 December 2012. As this law has been signed by President Obama, companies will need to record the impact of this change in the quarter ended 31 March 2010. PricewaterhouseCoopers (US) issued a DataLine (DL #2010-19) that describes the accounting considerations (under both US GAAP and IFRS) in more detail.
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