



Life Sciences

Accounting and Financial Reporting Update —
Interpretive Guidance on Revenue Recognition
Under ASC 605

March 2017

Revenue Recognition

Introduction

Many transactions in the life sciences industry must be carefully analyzed for revenue recognition purposes. Revenue recognition topics that are particularly relevant to life sciences entities include the SAB Topic 13¹ requirements (e.g., sales price is fixed or determinable, collectibility is reasonably assured); the accounting for multiple elements; the ability to estimate returns; and the accounting for discounts, rebates, and incentives. Further, biotech and pharmaceutical firms may sometimes encounter complexities related to the milestone method of accounting, the proportional performance method of revenue recognition, principal-agent considerations, license fees, contingent revenue, and up-front payments. Meanwhile, medical device companies may have to analyze warranties, shipping terms, consignment sales, customer financing, and the potential applicability of lease and software revenue recognition requirements.

Life sciences entities also rely heavily on collaborative arrangements to leverage expertise and manage risk. In accounting for collaborative arrangements under ASC 808, entities often also apply the revenue recognition guidance — for example, when:

- Performing a principal-agent analysis for transactions with third parties.
- Determining the unit of account, measurement, and recognition of transactions with the counterparty to the arrangement (if an entity analogizes to revenue recognition literature for such matters).
- Evaluating whether transactions with the counterparty to the arrangement are viewed as revenue activities (e.g., a biotech company performs contractual research and development (R&D) services for a pharmaceutical company under the arrangement).

The sections below discuss (1) guidance on some of the revenue recognition topics frequently encountered by life sciences entities, (2) SEC comment letter themes related to these topics, (3) anticipated changes in the life sciences industry as a result of the new revenue standard, and (4) an overview of the FASB's project on collaborative arrangements.

Industry Issues

Returns and Other Potential Adjustments to Revenue

The recognition of product revenue in the pharmaceutical (including biotechnology) industry relies heavily on estimates and assumptions about returns and other potential adjustments to revenue. Restatements and inquiries into the revenue recognition practices in the pharmaceutical industry underscore the need for entities to (1) focus on the criteria for recognizing revenue on the sale of pharmaceutical products and (2) consider various factors in estimating returns, chargebacks, rebates, discounts, promotions, shelf stock adjustments, and other adjustments to revenue.

¹ For the full titles of standards and other literature referred to in this publication, see [Appendix A](#). For a list of abbreviations used in this publication, see [Appendix B](#).

Reserves for returns may be more difficult to estimate in the pharmaceutical industry than in many other industries. The pharmaceutical company product sales terms generally include specific return policies (or policies are established through existing practice) that provide the terms under which the product can be returned. The product may be returned to the pharmaceutical company for a variety of reasons. One of the most common reasons is product expiration (which often occurs 18 to 30 months after product manufacturing).

Chargeback and rebate arrangements are also common in the pharmaceutical industry. Pharmaceutical companies often sell products to wholesalers (or distributors) under agreements containing various terms under which the products will be managed and sold, including specific pricing and return policies. Under these agreements, wholesalers purchase products from the pharmaceutical companies for resale to retailers (pharmacies, retail stores, or other consumer outlets), hospitals, clinics, and infusion centers.

For sales made to retailers, a wholesaler typically sells a product at wholesaler acquisition cost (WAC) plus a small markup. The retailer then sells the product to the ultimate consumer, who pays for the product directly or provides for payment through some type of insurance program (such as a managed-care or governmental program). The price paid by the ultimate consumer (through a combination of copays and insurance coverage) is often less than the price paid by the retailer to the wholesaler. As a result, retailers submit a rebate claim to the manufacturer for the difference between the price paid by the retailer and the negotiated health insurance cost of the product.²

For sales made to hospitals, clinics, and certain infusion centers, a wholesaler typically sells a product at a price negotiated by the entity (or through an intermediary, such as a group purchasing organization) and the pharmaceutical company. Because wholesalers purchase the product from the manufacturer at WAC but sell the product at a discounted price to their customers, wholesalers will “charge back” to the pharmaceutical company the difference between the wholesalers’ cost and the lower price at which the product was sold to the entity.

The discussion below gives an overview of the revenue recognition criteria applicable to arrangements involving a right of return, chargebacks, or rebates, including accounting considerations related to the sale of pharmaceutical products under these types of arrangements.

Revenue Recognition When a Right of Return Exists

As noted above, pharmaceutical companies generally give the buyer the ability to return a product under the terms of the sale agreement. ASC 605 provides guidance on how entities should account for sales of products when the buyer has a return privilege, whether as a matter of contract or in accordance with existing practice. ASC 605-15-25-1 specifies criteria for recognizing revenue when a right of return exists:

ASC 605-15

25-1 If an entity sells its product but gives the buyer the right to return the product, revenue from the sales transaction shall be recognized at time of sale only if all of the following conditions are met:

- a. The seller’s price to the buyer is substantially fixed or determinable at the date of sale.
- b. The buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product. . . .

² The actual submission process for claiming a rebate varies depending on the type of health coverage. For example, in managed markets, pharmacy benefit managers are commonly used, whereas for governmental programs, the claims are typically submitted by the states (often with the aid of a managed care plan, which acts as an administrator).

ASC 605-15 (continued)

- c. The buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product.
- d. The buyer acquiring the product for resale has economic substance apart from that provided by the seller. . . .
- e. The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer.
- f. The amount of future returns can be reasonably estimated

Sales revenue and cost of sales that are not recognized at time of sale because the foregoing conditions are not met shall be recognized either when the return privilege has substantially expired or if those conditions subsequently are met, whichever occurs first.

While all of the above criteria must be met for revenue to be recognized, the criteria in ASC 605-15-25-1(a) and ASC 605-15-25-1(f) require entities to use significant judgment in determining when to recognize revenue for products sold under many pharmaceutical arrangements. If a company determines that it cannot reasonably estimate returns, it cannot recognize revenue until the right of return expires or a reasonable estimate of returns can be made. Similarly, if a company determines that the price of the product is not determinable upon shipment to the wholesaler because it cannot estimate chargebacks and rebates, revenue would have to be deferred until the price can be determined. In both instances, such a determination requires careful consideration of all facts and circumstances that affect the sale of the product.

Ability to Reasonably Estimate Returns

Under ASC 605-15-25-1(f), an entity must be able to make a reasonable estimate regarding future returns to recognize revenue upon shipment of the product (provided that the other requirements of ASC 605 are met). ASC 605-15-25-3 indicates that the ability to make such an estimate depends on many factors and notes that the following factors may impair this ability:

- a. The susceptibility of the product to significant external factors, such as technological obsolescence or changes in demand
- b. Relatively long periods in which a particular product may be returned
- c. Absence of historical experience with similar types of sales of similar products, or inability to apply such experience because of changing circumstances, for example, changes in the selling entity's marketing policies or relationships with its customers
- d. Absence of a large volume of relatively homogeneous transactions.

As noted in ASC 605-15-25-4, while the existence of one or more of the factors listed in ASC 605-15-25-3 may not be sufficient to prevent an entity from making a reasonable estimate, other factors may prevent an entity from doing so. ASC 605-10-S99-1 discusses estimates and changes in estimates and provides the following additional factors to consider that may affect or preclude an entity's ability to make a reasonable and reliable estimate of product returns:

- Significant increases, or excess levels of inventory, in a distribution channel (sometimes referred to as "channel stuffing").
- Lack of "visibility" into, or the inability to determine or observe, the levels of inventory in a distribution channel and the current level of sales to end users.
- Expected introductions of new products that may result in the technological obsolescence, and larger than expected returns, of current products.

- The significance of a particular distributor to the registrant's (or a reporting segment's) business, sales, and marketing.
- The newness of a product.
- The introduction of competitors' products with superior technology or greater expected market acceptance.
- Other factors that affect market demand and changing trends in that demand for the registrant's products.

In addition, the Interpretive Response to Question 4 of SAB Topic 13.A.4(b) discusses the SEC staff's view on how long a history is necessary to estimate returns in a product sale transaction within the scope of ASC 605 and states:

The staff does not believe there is any specific length of time necessary in a product transaction. However, [ASC] 605-15 states that returns must be subject to reasonable estimation. Preparers and auditors should be skeptical of estimates of product returns when little history with a particular product line exists, when there is inadequate verifiable evidence of historical experience, or when there are inadequate internal controls that ensure the reliability and timeliness of the reporting of the appropriate historical information. Start-up companies and companies selling new or significantly modified products are frequently unable to develop the requisite historical data on which to base estimates of returns.

Further, the Interpretive Response to Question 5 of SAB Topic 13.A.4(b) discusses the SEC staff's view when a company selling products subject to a right of return concludes that it cannot reasonably estimate the actual return rate because of its limited history but can conservatively estimate the maximum possible returns:

If a reasonable estimate of future returns cannot be made, [ASC] 605-15 requires that revenue not be recognized until the return period lapses or a reasonable estimate can be made. Deferring revenue recognition based on the upper end of a wide range of potential return rates is inconsistent with the provisions of [ASC] 605-15. [Footnote omitted]

While not all of the factors in ASC 605 may apply directly to the sale of pharmaceutical products, many of the factors could significantly influence whether the product is ultimately returned. The following factors specific to the pharmaceutical industry could significantly affect the ability to estimate returns:

- Period in which returns can occur.
- Experiences with products (or the inability to apply such experiences to current products).
- Potential channel stuffing.
- Lack of information about product levels and age of product in the distribution channel.
- Predictability of market conditions and competition (e.g., competitive entry of a similar or generic product).
- Current stage in the product life cycle (i.e., initial product launch vs. end/maturity of product life).
- Historical, current, and projected demand.

The period and terms for product returns attributable to expiration may present particular challenges. The terms may specify, for example, that expiration returns may be made no sooner than 6 months before expiration and no later than 12 months after expiration. Under these common return practices, which may generate most of the returns, an entity may have to use significant judgment and may need significant data to reasonably estimate the returns reserve. Further, a review of subsequent return activity before issuance of the financial statements might be less useful for pharmaceutical companies

than it would be for most companies. This is because the expiration returns observed (e.g., in the first 2 months after year-end) might be related to sales that took place no sooner than 24 months earlier, if we assume a product life of 30 months from the date of sale.

Fully understanding the terms and conditions under which each product is being sold is key to determining whether revenue is being accounted for appropriately. The mere existence of factors cited in ASC 605 does not necessarily result in the inability to estimate returns. However, while there are no bright lines, sufficient evidence should exist to support the conclusion regarding the impact of each of these factors on the ability to estimate future returns. If there is not sufficient evidence of this ability, revenue should not be recognized until the right of return expires or there is sufficient evidence to estimate future returns.

Evaluating these factors for new product launches in the pharmaceutical industry may be even more challenging. The amount of historical information and evidence to support the estimates and assumptions regarding returns could be reduced depending on whether the product is (1) a modification of an existing product, (2) similar to other products in the market (i.e., an “analog”), or (3) a completely new product. Obtaining sufficient evidence for new products may be particularly difficult when the company does not have a relevant history for an analog or a clear competitive advantage that allows for more predictable sales. As noted above, the availability of sufficient evidence to support these estimates and assumptions is an important factor in having the ability to recognize revenue. Further, when using an analog to aid in the estimation of returns, life sciences entities are encouraged to document the basis for their conclusions that the analog is similar to the product being sold. Typically, this documentation should reflect that the analog is part of a similar therapeutic class, provides a similar mechanism of treatment, and targets similar customers and markets.

Ability to Reasonably Estimate Chargebacks and Rebates

In addition to estimating returns, entities must be able to make a reasonable estimate of potential adjustments to the price of the product, such as chargebacks and rebates. Although ASC 605 does not specifically address the accounting for pricing adjustments, ASC 605-15-25-1 requires the seller’s price to the buyer to be fixed or determinable for revenue to be recognized. As with the requirement of ASC 605-15-25-1(f), whether the price is determinable depends on the entity’s ability to reasonably estimate future adjustments to the amount billed for the product. This ability may be affected by many of the same factors that affect returns. Although ASC 605 does not provide specific factors to consider, the factors used in the evaluation of returns should also be used in the evaluation of whether the price is fixed or determinable, to the extent that those factors are applicable. The following factors may also be helpful in such an evaluation:

- Existence of product-specific historical information regarding chargebacks and rebates.
- Availability and specificity of customer-specific pricing information (including contractual arrangements with retailers, insurance providers, or governmental agencies).
- Information regarding the specific retailer and consumer product sales mix (to understand which customer pricing arrangement is applicable).
- Availability and specificity of customer inventory levels.

As with product returns, the nonexistence of one or more of the above factors, or the existence of one or more of the factors in ASC 605, does not necessarily result in the inability to estimate pricing adjustments. However, sufficient evidence should exist to ensure that the impact of these factors or similar factors does not change the conclusion that the price is fixed or determinable. If sufficient evidence does not exist to support such a conclusion, revenue should not be recognized until the price can be determined.



Thinking It Through

This guidance does not apply to potential adjustments to the price of the product that are based on future performance obligations or other contingencies. Such adjustments may be deemed contingent revenue and are subject to the guidance in ASC 605-15-25-1(e) or other authoritative literature.

Pay-for-Performance Arrangements

Pay for performance in health care gives financial incentives to clinicians for better health outcomes. Clinical outcomes, such as longer survival, can be difficult to measure, so pay-for-performance systems usually measure process outcomes. Also known as “value-based purchasing,” this payment model rewards physicians, hospitals, medical groups, and other health care providers for meeting certain performance measures for quality and efficiency. It penalizes caregivers for poor outcomes, medical errors, or increased costs. For example, if, after a defined treatment period, a patient does not exhibit the predetermined objective criteria, the drug manufacturer could be required to reimburse all or a portion of the amounts originally received upon sale of the drug.

Question

Can a vendor that enters into a pay-for-performance arrangement record revenue at the time of initial sale with a reserve for the portion of sales that it expects will not meet the previously determined criteria, or should revenue be deferred until the close of the refund period?

Answer

Revenue may be recognized at the time of initial sale if the vendor can demonstrate that it has sufficient historical basis to estimate the refunds to which the customer will be entitled. If the vendor does not have a company-specific historical basis to estimate refunds, revenue should be deferred until the close of the predetermined contingency period.

Multiple-Element Arrangements

Identifying Deliverables in a Multiple-Element Arrangement

ASC 605-25-15-2 states that the guidance in ASC 605-25 applies to “[a]ll deliverables (that is, products, services, or rights to use assets) within contractually binding arrangements (whether written, oral, or implied . . .).” Further, ASC 605-25-25-4 indicates that a “vendor shall evaluate all deliverables in an arrangement to determine whether they represent separate units of accounting.”

The term “deliverable,” however, is not defined. Accordingly, an entity must use judgment in determining whether an item in a multiple-element arrangement constitutes a deliverable. Throughout an arrangement, a vendor may commit to various “significant” performance obligations (e.g., obligations to provide products, provide services, or grant licenses), each of which may be likely to constitute a deliverable. An entity may also have various “less significant” or “ancillary” performance obligations under the arrangement. In addition, the terms of an arrangement could generally provide the parties with certain protective and other rights, such as a right to participate in a joint governance activity. The entity may need to consider such obligations to determine whether, on the basis of the specific facts and circumstances, they represent deliverables.

Question

What should a vendor consider when determining whether an item in a multiple-element arrangement constitutes a deliverable?

Answer

A vendor should consider the following as it analyzes an arrangement — viewed from the perspective of the customer (i.e., the other party to the arrangement) — to identify potential deliverables:

- Whether an item in the arrangement requires a distinct action from the vendor.
- Whether the exclusion of the item from, or the inclusion of the item in, the arrangement would cause the arrangement fee to vary by more than an insignificant amount.
- Whether the vendor’s failure to deliver an item results in (1) the customer’s receiving a full or partial refund, (2) the vendor’s incurring a contractual penalty, or (3) both.
- Whether all performance obligations (e.g., an obligation to provide a product, service, or right, either at a point in time or over the term of the arrangement) have been identified — particularly performance obligations that (1) may be considered ancillary to the “primary” product(s), service(s), or right(s) being sold or (2) do not have explicit monetary values assigned to them under the terms of the arrangement.
- The degree to which an item is essential to the functionality of other products, services, or rights being sold.
- Whether the customer considers an item significant or of value separately from other deliverables.

This list is not all-inclusive. When identifying deliverables, entities should evaluate the facts and circumstances of each arrangement. Notably, ASC 605-25 does not contain a materiality threshold for identifying deliverables in a multiple-element arrangement.

An example of an ancillary service obligation that could be considered a deliverable (that may or may not have a monetary value assigned to it) is an obligation to participate on a joint steering committee (or committees) throughout the term of the arrangement or without a defined term. Such an obligation is common in collaborative arrangements — particularly in the biotechnology and pharmaceutical industries. However, sometimes an entity may assess the substance and timing of the participation and conclude that such joint steering committee participation does not constitute a deliverable (i.e., the participation represents a right to joint governance for the mutual protection of each party’s interest rather than a service obligation). For example, the vendor may have the contractual right to withdraw from, and later rejoin, the joint steering committee without any financial consequences.

Once all deliverables in a multiple-element arrangement have been identified, a vendor should apply the provisions of ASC 605-25-25-5 to determine whether to consider each deliverable a separate unit of accounting.

Example

Company B enters into an arrangement with a customer to deliver highly specialized diagnostic equipment. The arrangement requires that upon installation of the equipment, all testing of the equipment must occur at the customer's location. Company B has previously sold the same equipment separately to other customers, and other vendors can perform the installation of the equipment.

When determining what elements of the arrangement constitute deliverables, B would assess the equipment, installation, testing, and other contractual terms of the arrangement. Company B determines that the equipment and the installation are both deliverables because both are sold separately in the marketplace.

Company B would consider the factors above, among others, when determining whether the testing represents a deliverable. If, during the testing of the product, B allowed the customer's employees to consult its installation technicians about key troubleshooting techniques associated with the equipment and the customer acquired knowledge during that process, B may conclude that the testing is a deliverable that it must evaluate under ASC 605-25. That is, B may conclude that the testing is important, has value to the customer, and therefore would cause the arrangement fee to vary by more than an insignificant amount.

Conversely, if the testing of the equipment was a standardized process that is considered perfunctory and results in no transfer of knowledge to the customer, B may conclude that the testing (1) is simply a quality-control function inseparable from the equipment itself and (2) should not be evaluated as a separate deliverable under ASC 605-25.

Contingent Deliverables

Question

Is a contingency in a multiple-element revenue arrangement a deliverable that an entity should evaluate under ASC 605-25?

Answer

A contingency in a revenue arrangement may represent a potential deliverable that may be difficult to analyze under ASC 605-25. The EITF discussed this topic during its deliberations of the guidance (codified by [ASU 2009-13](#)) but ultimately decided not to address contingencies in an arrangement with multiple deliverables, observing that accounting conclusions on this topic are highly dependent on individual facts and circumstances.

The "Issue 08-1 Working Group," which advised the EITF on this topic, described a contingent deliverable as a revenue-generating activity that is contingent on the occurrence of a future event not exclusively within the control of the customer. If the future event occurs, the vendor is required by the terms of the arrangement to deliver specified products or services. In describing contingent deliverables, the working group noted that such deliverables can be contingent on (1) the actions of a party unrelated to the revenue arrangement (such as a governmental agency), (2) the vendor's actions, or (3) a combination of both. In some industries and arrangements, contingent deliverables may be prevalent and represent deliverables with considerable value.

The examples below illustrate contingencies that could be considered deliverables under ASC 605-25.

Example 1

Company B is a biotech company that has developed a new technology for monitoring and testing diabetic individuals. Company B grants Customer X a five-year license to its technology. The terms of the license agreement do not require B (i.e., B is not obligated) to perform any additional R&D activities. However, B agrees (i.e., B has a contingent obligation) that if improvements to its technology are made during the next two years, it will provide X with a license to the updated technology on a when-and-if-available basis. Any new license granted to X will terminate at the same time as the original five-year license.

On the basis of all of the facts and circumstances, B determines that the obligation to provide a license for improvements to its technology on a when-and-if-available basis represents a deliverable that must be evaluated and accounted for under ASC 605-25.

Example 2

Company C enters into an arrangement in which it agrees (i.e., has an obligation) to provide R&D services to Customer Y on a best-efforts basis for three years. If a commercially viable product is developed as a result of those services, C agrees to manufacture 100 units of the product and deliver them (i.e., has a contingent obligation) to Y. The manufacturing process performed by C is novel since similar manufacturing capabilities are not available in the marketplace. Customer Y agrees to pay C \$1 million for the R&D services.

On the basis of all of the facts and circumstances, C determines that the obligation to manufacture and deliver 100 units if a commercially viable product is developed represents a deliverable that must be evaluated and accounted for under ASC 605-25.

Optional Purchases

Question

An optional purchase is a term in an arrangement that gives a customer the option to purchase products or services in the future. Is an optional purchase a deliverable that an entity should evaluate under ASC 605-25?

Answer

It depends. If a revenue-generating arrangement contains an option to buy products or services in the future and the substance of the arrangement is that the customer truly can elect whether to purchase any of those products or services, the option should be evaluated as a separate arrangement and not as a deliverable of the original arrangement. An entity should evaluate the substance of an arrangement in determining whether an optional purchase of future products or services represents a deliverable.

An entity should analyze all relevant facts and circumstances in determining the substance of the arrangement, such as whether the contractual option to purchase the product or service in the future is truly optional to the customer. If, in substance, the option to buy the future product or service is not truly optional because the customer has no choice but to purchase the future product or service, the optional purchase of future products or services would be considered a deliverable of the original arrangement. For example, if an arrangement gave a customer the option to purchase future products

or services and those future products and services were necessary for the intended use of the delivered product and not readily obtainable from another party, the optional purchase of future products and services would be considered a deliverable of the original arrangement.

If an arrangement's contractual terms represent options to purchase future products and services in which the quantity ultimately purchased is variable but the customer does not really have the option not to buy the product or service in the future, an entity would conclude that those options represent deliverables of the original arrangement. In addition, if an optional purchase of products or services in the future is considered a deliverable because the future products or services are necessary for the intended use of the delivered product and not readily obtainable from another party, concerns may be raised about whether the delivered item has stand-alone value and whether the arrangement could be separated into multiple units of accounting.

Example

A vendor sells medical equipment to a customer. To function, the medical equipment needs cartridges that are only sold by the vendor. The arrangement gives the customer the option of purchasing these cartridges from the vendor. On the basis of all the facts and circumstances, the vendor determines that the customer's purchase of cartridges in the future is not truly optional because they are required for the intended use of the equipment and are only sold by the vendor. Therefore, the vendor determines that the optional purchase of the cartridges represents a deliverable in the original arrangement that must be evaluated. The vendor should also carefully evaluate whether the medical equipment has stand-alone value given that its functionality depends on the subsequent delivery of the cartridges.

If the optional purchase is not considered a deliverable of the original arrangement, the vendor should still consider whether a discount on optional purchases is present and whether the discount creates a deliverable. In some arrangements, a vendor may provide significant incremental discounts (i.e., discounts above those that are usually provided in comparable transactions and above any discounts related to other elements in the arrangement) on future purchases of products or services. For guidance on how to account for significant incremental discounts, see ASC 985-605-55-82 through 55-85 and ASC 985-605-55-185 through 55-200.

Multiple-Element Arrangement Example — Licensing and Supply Arrangement

Company B develops, licenses, manufactures, and sells pharmaceutical products. Company B enters into a separate licensing and supply agreement with an unrelated third-party company (the "distributor") to market and sell B's product. The provisions of the licensing agreement are as follows:

- The distributor is responsible for obtaining approval from the relevant regulatory agencies to market and sell B's product. Proprietary product information required by the regulatory agencies will be provided to the distributor.
- The distributor may not obtain any ownership rights to the proprietary information and is prohibited from selling, subleasing, assigning, or otherwise transferring its rights to the proprietary product information licensed from B.

The separate supply agreement stipulates the following:

- The product will be marketed and sold under the distributor's name.
- The distributor must purchase all of its supply of the product from B at a specified price index for a minimum of 10 years commencing on the date regulatory approval is obtained.
- The distributor may not manufacture the product in-house.
- The distributor is not permitted to market, sell, or distribute similar products sourced from an alternative supplier.

The licensing agreement requires the distributor to pay B an up-front licensing fee. A portion of this fee (66 percent) is refundable if the distributor is unable to receive regulatory approval to market and sell B's product. Payments for the product are due as the distributor purchases its supply for resale from B.

Question

Should the separate deliverables — the license and product — be accounted for as separate units of accounting?

Answer

No. The license has no stand-alone value since the distributor has no ability to resell it and is not allowed to use it to manufacture or source the product from anyone but B. Accordingly, the license and product should be accounted for as one combined unit of accounting for revenue recognition purposes, in accordance with ASC 605-25-25-5 and 25-6, which state the following:

ASC 605-25

25-5 In an arrangement with multiple deliverables, the delivered item or items shall be considered a separate unit of accounting if both of the following criteria are met:

- a. The delivered item or items have value to the customer on a standalone basis. The item or items have value on a standalone basis if they are sold separately by any vendor or the customer could resell the delivered item(s) on a standalone basis. In the context of a customer's ability to resell the delivered item(s), this criterion does not require the existence of an observable market for the deliverable(s).
- b. Subparagraph superseded by [ASU] 2009-13³
- c. If the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item or items is considered probable and substantially in the control of the vendor. . . .

25-6 A delivered item or items that do not qualify as a separate unit of accounting within the arrangement **shall be combined** with [the amount allocable to] the other applicable undelivered item(s) within the arrangement. **The allocation of arrangement consideration and the recognition of revenue then shall be determined for those combined deliverables as a single unit of accounting.** [Emphasis added]

³ ASU 2009-13 eliminated the criterion formerly in ASC 605-25-25-5(b) that stated, "There is objective and reliable evidence of fair value of the undelivered item(s)."

SEC Comment Letter Themes Related to Multiple-Element Arrangements

Examples of SEC Comments

- Please tell us your assessment of the applicability of Accounting Standards Codification Topic 605-25: Revenue Recognition from Multiple-Element Arrangements to your 2015 agreements.
- You state that you consider the sales discounts under your initial order reward program to be part of a multiple element arrangement and [that they] accordingly are deferred when the first order is placed and recognized as customers place their subsequent two orders. Please tell us:
 - [T]he reason you believe the transaction is a multiple element arrangement under ASC 605-25;
 - [H]ow you determine the amount to defer under that accounting and how it compares to the contractual amount of the discount earned (i.e. same, higher, lower); and
 - [H]ow your method of recognizing these discounts as customers place their subsequent two orders complies with ASC 605-50-25.

Please provide us an example of your calculations and the respective journal entries.

The SEC staff often asks registrants about the nature of, and accounting for, their multiple-element arrangements and how they evaluated these arrangements under ASC 605-25. The staff typically asks for additional information and sometimes requests more disclosure about multiple-element arrangements, including:

- A description of the registrant's rights and obligations under the arrangement.
- The registrant's method for determining whether certain deliverables in an arrangement qualify as separate units of accounting and the factors the registrant considered in making this assessment.
- The registrant's accounting policy for allocating and recognizing revenue for each deliverable.
- The registrant's support for its conclusion that a delivered item has stand-alone value.
- An analysis of how the transaction price was allocated to each deliverable, including how the selling price used for each unit of accounting was determined (i.e., vendor-specific objective evidence, third-party evidence, or estimated selling price).
- The period over which each unit of accounting is recognized.

The SEC staff has also focused on registrant's accounting for up-front fees. It has asked registrants to explain whether such fees are related to specific performance obligations and how they determined the period over which the up-front fees are recognized. For more information about multiple-element arrangements and other revenue-related considerations, see the "Revenue Recognition" section in Deloitte's *SEC Comment Letters — Including Industry Insights: What "Edgar" Told Us (Ninth Edition)*, as well as Deloitte's *SEC Comment Letters — Statistics According to "Edgar": Supplement to the Ninth Edition*.

Milestone Method of Revenue Recognition

Life sciences entities frequently enter into arrangements involving R&D deliverables in which all or part of the consideration becomes due upon the achievement of certain events or conditions, which are often referred to as milestones.

Question

What considerations are relevant to the determination of when payments that become due upon the achievement of milestones should be recognized in revenue?

Answer

As stated in ASC 605-28-15-2, ASC 605-28 “applies to research or development deliverables or units of accounting under which a vendor satisfies its performance obligations over a period of time, and when a portion or all of the consideration is contingent upon uncertain future events or circumstances.”

The glossary in ASC 605-28-20 defines a milestone as follows:

ASC 605-28
<p>Milestone</p> <p>An event having all of the following characteristics:</p> <ol style="list-style-type: none">There is substantive uncertainty at the date the arrangement is entered into that the event will be achieved. A vendor’s assessment that it expects to achieve a milestone does not necessarily mean that there is not substantive uncertainty associated with achieving the milestone.The event can only be achieved based in whole or in part on either of the following:<ol style="list-style-type: none">The vendor’s performanceA specific outcome resulting from the vendor’s performance.If achieved, the event would result in additional payments being due to the vendor. <p>A milestone does not include events for which the occurrence is either of the following:</p> <ol style="list-style-type: none">Contingent solely upon the passage of timeThe result of a counterparty’s performance.

ASC 605-28 requires a milestone to be “substantive” for milestone consideration to be recognized in its entirety in the period in which the milestone is achieved. Specifically, ASC 605-28-25-2 notes that the “consideration earned from the achievement of a milestone shall meet all of the following conditions for the milestone to be considered substantive:”

- It is commensurate with either of the following:
 - The vendor’s performance to achieve the milestone
 - The enhancement of the value of the delivered item or items as a result of a specific outcome resulting from the vendor’s performance to achieve the milestone.
- It relates solely to past performance.
- It is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

In addition, ASC 605-28-25-3 explains that a milestone is not substantive “if any portion of the associated milestone consideration relates to the remaining deliverables in the unit of accounting (that is, it does not relate solely to past performance). . . . [I]f a portion of the consideration earned from achieving a milestone may be refunded or adjusted based on future performance (for example, through a penalty or clawback), the contingent consideration is not considered to relate solely to past performance, and, thus, the related milestone cannot be considered substantive.”

Further, ASC 605-28-25-1 notes that “a vendor is not precluded from making an accounting policy election to apply a different policy that results in the deferral of revenue relating to some portion of the milestone consideration” even if the criteria in ASC 605-28 are met.

SEC Comments Letter Themes Related to the Milestone Method

Example of an SEC Comment

Your disclosure . . . lists the awarding of a license as an example of an appropriate milestone for revenue recognition. Please provide us with a detailed explanation of your basis for previously recognizing this revenue, including the specific milestones previously reached that made recognition of the revenue on the affected contracts appropriate. Also, please clarify your ongoing revenue recognition policy in terms of when it is appropriate to recognize revenue prior to obtain[ing] a license.

The SEC staff has continued to comment on disclosures related to the milestone method of revenue recognition under ASC 605-28. When such disclosures apply, the SEC staff will review the registrant's filings to determine whether they contain the following disclosures outlined in ASC 605-28-50-2:

- a. A description of the overall arrangement
- b. A description of each milestone and related contingent consideration
- c. A determination of whether each milestone is considered substantive
- d. The factors that the entity considered in determining whether the milestone or milestones are substantive
- e. The amount of consideration recognized during the period for the milestone or milestones.

Registrants in the industry will often make adjustments for milestones when determining non-GAAP income. For a discussion of adjustments made by registrants when determining their non-GAAP measures, see the “Non-GAAP Financial Measures and Key Metrics” section in Deloitte’s [*SEC Comment Letters — Including Industry Insights: What “Edgar” Told Us \(Ninth Edition\)*](#).

Medical Device Excise Tax

As a result of the Patient Protection and Affordable Care Act of 2010, Section 4191 of the Internal Revenue Code imposes a 2.3 percent excise tax on sales of certain medical devices by manufacturers, producers, or importers of the devices. This tax is referred to as the medical device excise tax (MDET). The MDET has been in effect since 2013, but the Protecting Americans From Tax Hikes Act of 2015, which was signed into law in December 2015, includes a two-year suspension of the tax, which applies to sales on or after January 1, 2016, and before January 1, 2018.

Question

Is the MDET within the scope of ASC 605-45?

Answer

Whether the MDET is within the scope of ASC 605-45 depends on how it is incurred. Because the MDET is imposed on the basis of an individual legal entity, the tax can be triggered by both third-party and intercompany sales. Therefore, in evaluating the applicability of ASC 605-45, an entity will need to determine whether the tax is imposed on a sale to a customer (a third-party sale) or before a sale to a customer (an intercompany sale):

- *Third-party sales* — When the MDET is imposed on a third-party sale, it would be within the scope of ASC 605-45. Accordingly, an entity may elect (or may have already elected) as an accounting policy to present the tax “on either a gross basis (included in revenues and costs) or a net basis (excluded from revenues)” in accordance with ASC 605-45-50-3.
- *Intercompany sales* — When the MDET is imposed on an intercompany sale, it would be outside the scope of ASC 605-45 because the tax is not assessed “on and concurrent with a specific revenue-producing transaction between a seller and a customer” in accordance with ASC 605-45-15-2(e). In such circumstances, some entities may view the MDET as a cost of preparing the medical device for sale, in which case capitalization of the MDET into inventory may be permitted (until a third-party sale occurs) under ASC 330.

As entities evaluate their accounting for the MDET, they should determine whether they have an existing policy for excise taxes with characteristics similar to those of the MDET and, if so, should consider whether to apply this policy to their accounting for the MDET.

Medicare Coverage Gap Discounts

As a result of the Patient Protection and Affordable Care Act, entities participating in Medicare Part D must provide Medicare beneficiaries in the Medicare coverage gap (or “donut hole”) with a 50 percent discount in their Medicare prescription drug coverage.

Question

How should an entity recognize discounts related to the Medicare coverage gap?

Answer

No accounting literature directly addresses the accounting for discounts offered to individuals in the Medicare coverage gap. However, we believe that there are two acceptable models for such accounting:

- An entity may apply the “specific identification” (or “point-of-sale”) model by estimating which sales of prescription drugs are to individuals expected to be in the Medicare coverage gap and recognizing the respective discount as a reduction of revenue for those sales. Under this model, the discount provided to the individual in the Medicare coverage gap is attributed to the specific party (i.e., the particular Medicare beneficiary) that would have been considered the payer. Accordingly, the discount is recognized in a manner similar to how the entity recognizes other discounts or pricing adjustments that would be attributed to other payers. In applying this method, the entity must estimate when the coverage gap payment would be triggered on the basis of its product portfolio and sales volumes and record that estimate in the initial quarter that is affected.

- An entity may apply a “spread” (or “effective rate”) model in which it estimates the total discount to be provided to individuals in the Medicare coverage gap for the annual period and uses a systematic and rational allocation method to recognize that discount as a reduction of revenue for sales that are attributed to Medicare beneficiaries (e.g., ratably as a percentage of all sales to Medicare beneficiaries during the year). The discount provided while the individual is in the Medicare coverage gap is considered similar to a contingent sales incentive, as discussed in ASC 605-50, on the basis that the discount agreement is a condition of participating in Medicare Part D and that such discounts are attributable to all respective Medicare revenues for the year. Under this method, entities could potentially record the impact before the quarterly period in which the gap coverage is actually triggered. In addition, the impact could go beyond the upper limit of the coverage gap because the entity is applying a ratable approach.

An entity should use either the specific identification model or the spread model for the discounts associated with sales attributed to the Medicare coverage gap and should apply the method consistently.

Collaborative Arrangements

As life sciences entities continue to adapt to an ever-changing marketplace, some may increasingly look to enter into or expand collaborations with third parties for the development or commercialization of certain drug candidates or medical products in an effort to share in both the costs and risks associated with such activities.

In collaborations, the parties may allocate responsibility for individual activities to each other or share the responsibility for one or more activities under a joint operating arrangement. Joint operating activities may involve the joint development and ultimate commercialization of intellectual property related to a potential new drug candidate, R&D, marketing (including promotional activities and physician detailing), general and administrative activities, manufacturing, and distribution activities. On the basis of contractually defined terms, the participants share in the profits or losses associated with these joint activities.

Such arrangements are often complex and can vary significantly in scope, terms, and conditions as well as risk mitigation objectives. The following are common forms of these arrangements:

- *Codevelopment and comarketing arrangements* — Joint operating agreements in which both parties to the agreement assume roles and responsibilities.
- *Copromotion arrangements* — Agreements in which companies partner together and use each company’s commercial capabilities and experience to promote a product (owned by one of the parties) in various markets.

Question

What considerations pertain to the accounting for a collaborative arrangement?

Answer

When an entity enters into a collaboration, management must consider whether the arrangement meets the U.S. GAAP definition of a collaborative arrangement to determine whether the arrangement is subject to the requirements of ASC 808. The legal characterization of an arrangement (e.g., as a collaboration or a collaborative arrangement) does not necessarily cause it to meet the definition of a collaborative arrangement under U.S. GAAP.

ASC 808-10-20 defines a collaborative arrangement as a “contractual arrangement that involves a joint operating activity” and involves two (or more) parties that are both:

- “[A]ctive participants in the activity.”
- “[E]xposed to significant risks and rewards dependent on the commercial success of the activity.”

On the basis of these criteria, some types of collaborations in the industry may not meet the definition of a collaborative arrangement and therefore would not be within the scope of ASC 808. For example, certain arrangements in which one party solely provides financial resources for an endeavor and is generally not an active participant would not meet the definition of a collaborative arrangement. Alternatively, arrangements between two parties that involve codevelopment, comarketing, or copromotion activities, as well as the sharing of risks and rewards based on the success of such activities, would generally meet the definition of a collaborative arrangement.

A collaboration can begin at any point in the life cycle of an endeavor (e.g., during the R&D phase or after a drug has been commercially launched). The facts and circumstances associated with the arrangement will dictate whether the parties (1) represent active participants and (2) are exposed to significant risks and rewards.

ASC 808-10-15-8 cites the following examples of situations in which active participation may exist:

- a. Directing and carrying out the activities of the joint operating activity
- b. Participating on a steering committee or other oversight or governance mechanism
- c. Holding a contractual or other legal right to the underlying intellectual property.

In addition, ASC 808-10-15-11 lists circumstances that might indicate that participants are not exposed to significant risks and rewards:

- a. Services are performed in exchange for fees paid at market rates.
- b. A participant is able to exit the arrangement without cause and recover all (or a significant portion) of its cumulative economic participation to date.
- c. Initial profits are allocated to only one participant.
- d. There is a limit on the reward that accrues to a participant.

Further, according to ASC 808-10-15-12, an entity should also consider other factors when evaluating participants’ exposure to significant risks and rewards, including (1) the “stage of the endeavor’s life cycle” and (2) the “expected duration or extent of the participants’ financial participation . . . in relation to the endeavor’s total expected life or total expected value.”

For collaborations that meet the definition of a collaborative arrangement, ASC 808 provides guidance on income statement presentation, classification, and disclosures. However, ASC 808 does not address recognition or measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met. Thus, even when a collaboration is within the scope of ASC 808, entities must look to other GAAP (possibly by analogy) to determine the appropriate recognition and measurement for the activities subject to the arrangement.

An entity’s accounting for a collaborative arrangement may also depend on whether there are any activities under the arrangement for which the entity and the counterparty have a customer-vendor relationship. For example, as part of a collaborative arrangement for which a biotech company and

pharmaceutical company agree to coproduce and commercialize a newly approved drug, the biotech company may also agree to provide the pharmaceutical company with R&D services that represent the biotech company's ongoing major or central operations. In such cases, it may be appropriate for the biotech company to apply revenue recognition guidance when recognizing and measuring the R&D services if the pharmaceutical company is deemed a customer for this element in the overall collaborative arrangement.

In the accounting for payments between counterparties in a collaborative arrangement, questions have arisen regarding whether the presence of loss-sharing provisions during commercialization could affect whether any consideration received, including up-front payments deemed "nonrefundable," would not be considered fixed or determinable (and therefore would be treated as either a liability or deferred revenue depending on the facts and circumstances). Arrangement consideration may not be fixed or determinable if an entity concludes that the loss-sharing provision requires the recipient to effectively refund all or a portion of the consideration received when (1) the collaboration incurs losses in commercialization and (2) loss-sharing payments are required to be made to the party that paid the consideration.

We believe that in assessing whether consideration received is fixed or determinable, an entity should consider, among other factors, the stage of the endeavor and the likelihood of the future loss-sharing payments under the arrangement. For example, an entity may determine that an up-front payment received at the outset of an R&D and commercialization arrangement is fixed and determinable if (1) there is significant uncertainty that commercialization is unlikely at the outset of the agreement given the early stage of development of the compound (and, therefore, the loss-sharing provision would never apply) or (2) commercialization is expected to be profitable. However, if consideration (i.e., an up-front payment) is received in connection with an arrangement entered into at or near the time of regulatory approval of a drug whose commercialization is expected to result in losses, and the arrangement requires the party receiving the up-front payment to share in losses, such party is effectively refunding the up-front consideration and would generally conclude that the consideration is not fixed or determinable regardless of whether the consideration, in form, is referred to in the arrangement as nonrefundable.

When determining the appropriate income statement presentation of amounts recorded as a result of a collaborative arrangement, entities also will need to separately evaluate (1) transactions with third parties outside of the arrangement and (2) transactions between collaboration participants. ASC 808 requires that each collaboration participant report costs incurred and revenue generated from transactions with third parties in its income statement in accordance with the principal-versus-agent guidance in ASC 605-45. The participant in the collaborative arrangement that is deemed the principal participant for a given transaction should record the transaction on a gross basis in its financial statements, notwithstanding the presence of cost sharing or cost allocation of such amounts on the basis of the terms of the agreement.

Participants also need to evaluate the appropriate income statement presentation for payments between the collaboration partners (e.g., as a result of expense reimbursements or profit sharing). When such payments are within the scope of other authoritative accounting literature, entities should apply the income statement classification requirements by using the relevant provisions of that literature. If the payments are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on an analogy to authoritative accounting literature or — if there is no appropriate analogy — a reasonable, rational, and consistently applied accounting policy election.

We believe that when an entity makes an analogy to authoritative accounting literature, all (as opposed to limited) aspects of that literature should be applied to the extent applicable. For example, a biotech company may enter into a collaborative arrangement with a pharmaceutical company and, as part of the collaboration, (1) provide the pharmaceutical company a license to use intellectual property related to a drug candidate and (2) perform R&D services jointly with the pharmaceutical company. The biotech company may conclude that the revenue literature is applicable by analogy for determining the unit(s) of accounting, recognition, and measurement. Accordingly, if the biotech company concludes that the license does not have stand-alone value apart from the R&D services to be performed, the revenue literature would require the license and R&D services to be combined for accounting purposes. Further, with respect to the appropriate income statement presentation for consideration allocated to the combined unit of accounting (in this case, the license and R&D services), such consideration would generally be presented consistently in the same category for income statement presentation purposes given the conclusion that the license and R&D services should be combined for accounting purposes.

SEC Comment Letter Themes Related to Collaborative Arrangements

Examples of SEC Comments

- In order to help us understand more fully how your collaborative arrangements impact your financial statements for each period presented, please provide us, in table format, the amounts . . . by year and by line item included in your statements of operations attributable to transactions arising from collaborative arrangements between you and the other participants and third-parties. Please provide separate tables for each of your “significant” collaborative arrangements and for all of your collaborative arrangements in the aggregate (i.e. the “significant” arrangements and all other arrangements). Present separately amounts with other participants and third-parties that are netted in a financial statement line item.
- You indicate that collaborative activities may include research and development, marketing and selling (including promotional activities and physician detailing), manufacturing, and distribution. Tell us your accounting policies regarding separation and allocation for your collaborative arrangements.
- Although you disclose your accounting policies for income you generate as a result of collaboration agreements under “revenue recognition” . . . , tell us your accounting recognition for other aspects of these arrangements and where these policies are disclosed.
- [Y]ou disclose that you recently entered into collaboration agreements Please discuss the material terms of these agreements and file them as exhibits. Alternatively, provide us with an analysis supporting your determination that you are not required to file them as exhibits.

Collaborative arrangements are common among biotech and pharmaceutical companies. As a result, the SEC staff often asks registrants in the industry about the nature of, and accounting for, their collaborative arrangements and has continued to probe them to better understand the basis for such accounting under U.S. GAAP.

Inquiries to registrants have focused on the registrant’s conclusion about whether certain transactions with the collaboration partner represent true vendor-customer activities. Collaborative arrangements within the scope of ASC 808 are based on the premise that each party to the agreement assumes a proportionate share of risks and, therefore, a vendor-customer relationship does not exist. Even if the registrant concludes that it is a party to a collaborative agreement, however, there may be circumstances in which certain elements of the agreement represent activities that are similar to those in a vendor-customer relationship. Accordingly, the SEC staff seeks to understand the registrant’s accounting policies regarding separation (i.e., unit of accounting) and allocation (i.e., when multiple units exist) for collaborative arrangements.

In addition, since collaborative arrangements often include up-front payments, royalty or profit-share payments, and expense reimbursements, the SEC staff has requested supplemental explanation of the registrant's determination and disclosure of (1) the separation, allocation, recognition, and classification principles that were used to account for payments between collaboration partners and (2) the factors that led the registrant to conclude that it is the principal (or agent) in transactions with third parties.

The SEC staff has also requested enhanced disclosures about registrants' collaborative agreements, including the overall effect of collaborative arrangements on the financial statements. SEC staff requests for such disclosures have focused on clearly describing the material terms of a collaborative arrangement, such as (1) each party's rights and obligations under the arrangement, (2) potential payments, (3) the existence of royalty provisions, and (4) duration and termination provisions. Further, the SEC staff has asked that registrants prepare a tabular summary to provide it with a composite disclosure of the financial statement impact of all collaborative arrangements. For all periods presented, the SEC staff may request a separate table for each significant collaborative arrangement and a table for all collaborative arrangements in the aggregate; in addition, the SEC staff may request separate presentation in such tables of amounts attributable to transactions with other participants and third parties that are presented net in a financial statement line item.

Further, the SEC staff may ask registrants to file a material collaborative arrangement as an exhibit to their filing in accordance with SEC Regulation S-K, Item 601(b)(10). For more discussion, see the "Material Contracts" section of Deloitte's *SEC Comment Letters — Including Industry Insights: What "Edgar" Told Us (Ninth Edition)*, as well as Deloitte's *SEC Comment Letters — Statistics According to "Edgar": Supplement to the Ninth Edition*.

Appendix A — Glossary of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

AICPA Literature

Accounting and Valuation Guide *Assets Acquired to Be Used in Research and Development Activities*

FASB Accounting Standards Updates

ASU 2017-05, *Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets*

ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers*

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash — a consensus of the FASB Emerging Issues Task Force*

ASU 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments — a consensus of the Emerging Issues Task Force*

ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

ASU 2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

ASU 2016-11, *Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting*

ASU 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*

ASU 2016-08, *Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)*

ASU 2016-07, *Investments — Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting*

ASU 2016-03, *Intangibles — Goodwill and Other (Topic 350), Business Combinations (Topic 805), Consolidation (Topic 810), Derivatives and Hedging (Topic 815): Effective Date and Transition Guidance — a consensus of the Private Company Council*

ASU 2016-02, *Leases (Topic 842)*

ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*

ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*

ASU 2015-14, *Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date*

ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*

ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*

ASU 2014-18, *Business Combinations (Topic 805): Accounting for Identifiable Intangible Assets in a Business Combination — a consensus of the Private Company Council*

ASU 2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity — a consensus of the FASB Emerging Issues Task Force*

ASU 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*

ASU 2014-09, *Revenue From Contracts With Customers (Topic 606)*

ASU 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*

ASU 2014-07, *Consolidation (Topic 810): Applying Variable Interest Entities Guidance to Common Control Leasing Arrangements — a consensus of the Private Company Council*

ASU 2014-03, *Derivatives and Hedging (Topic 815): Accounting for Certain Receive-Variable, Pay-Fixed Interest Rate Swaps — Simplified Hedge Accounting Approach — a consensus of the Private Company Council*

ASU 2014-02, *Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council*

ASU 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements — a consensus of the FASB Emerging Issues Task Force*

FASB ASC Topics and Subtopics

ASC 205, Presentation of Financial Statements

ASC 205-20, Presentation of Financial Statements: Discontinued Operations

ASC 230, Statement of Cash Flows

ASC 230-10, Statement of Cash Flows: Overall

ASC 235, Notes to Financial Statements

ASC 250, Accounting Changes and Error Corrections

ASC 250-10, Accounting Changes and Error Corrections: Overall

ASC 280-10, Segment Reporting: Overall

ASC 320, Investments — Debt and Equity Securities

ASC 321-10, Investments — Equity Securities: Overall

ASC 323-10, Investments — Equity Method and Joint Ventures: Overall

ASC 325-10, Investments — Other: Overall

ASC 325-40, Investments — Other: Beneficial Interests in Securitized Financial Assets

ASC 326-20, Financial Instruments — Credit Losses: Measured at Amortized Cost

ASC 326-30, Financial Instruments — Credit Losses: Available-for-Sale Debt Securities

ASC 330, Inventory

ASC 330-10, Inventory: Overall

ASC 350, Intangibles — Goodwill and Other

ASC 350-30, Intangibles — Goodwill and Other: General Intangibles Other Than Goodwill

ASC 360-10, Property, Plant, and Equipment: Overall

ASC 450, Contingencies

ASC 450-10, Contingencies: Overall

ASC 450-20, Contingencies: Loss Contingencies

ASC 450-30, Contingencies: Gain Contingencies

ASC 470-10, Debt: Overall

ASC 470-20, Debt: Debt With Conversion and Other Options

ASC 480-10, Distinguishing Liabilities From Equity: Overall

ASC 605, Revenue Recognition

ASC 605-10, Revenue Recognition: Overall

ASC 605-15, Revenue Recognition: Products

ASC 605-25, Revenue Recognition: Multiple-Element Arrangements

ASC 605-28, Revenue Recognition: Milestone Method

ASC 605-45, Revenue Recognition: Principal Agent Considerations

ASC 605-50, Revenue Recognition: Customer Payments and Incentives

ASC 606, Revenue From Contracts With Customers

ASC 606-10, Revenue From Contracts With Customers: Overall

ASC 610-20, Other Income: Gains and Losses From the Derecognition of Nonfinancial Assets

ASC 730, Research and Development

ASC 730-10, Research and Development: Overall

ASC 730-20, Research and Development: Research and Development Arrangements

ASC 740, Income Taxes

ASC 740-10, Income Taxes: Overall

ASC 740-270, Income Taxes: Interim Reporting

ASC 805, Business Combinations

ASC 805-10, Business Combinations: Overall

ASC 805-20, Business Combinations: Identifiable Assets and Liabilities, and Any Noncontrolling Interest

ASC 805-30, Business Combinations: Goodwill or Gain From Bargain Purchase, Including Consideration Transferred

ASC 805-50, Business Combinations: Related Issues

ASC 808, Collaborative Arrangements

ASC 808-10, Collaborative Arrangements: Overall

ASC 810, Consolidation

ASC 810-10, Consolidation: Overall

ASC 810-20, Consolidation: Control of Partnerships and Similar Entities

ASC 810-30, Consolidation: Research and Development Arrangements

ASC 815, Derivatives and Hedging

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 915, *Development Stage Entities*

ASC 915-10, *Development Stage Entities: Overall*

ASC 985-605, *Software: Revenue Recognition*

FASB Proposed Accounting Standards Updates

Proposed ASU 2017-200, *Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)*

Proposed ASU 2017-210, *Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory*

Proposed ASU 2016-270, *Income Taxes (Topic 740) Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes*

Proposed ASU 2015-340, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

Proposed ASU 2015-310, *Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material*

Other FASB Proposal

Proposed Concepts Statement 2014-200, *Conceptual Framework for Financial Reporting: Chapter 8: Notes to Financial Statements*

FASB Statements (Pre-Codification Literature)

Statement No. 167, *Amendments to FASB Interpretation No. 46(R)*

Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51*

Statement No. 141(R), *Business Combinations*

FASB Interpretation (Pre-Codification Literature)

FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*

FASB Concepts Statements

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 6, *Elements of Financial Statements*

EITF Issues

Issue 09-4, "Seller Accounting for Contingent Consideration"

Issue 08-1, "Revenue Arrangements With Multiple Deliverables"

Issue 04-5, "Determining Whether a General Partner, or the General Partners as a Group, Controls a Limited Partnership or Similar Entity When the Limited Partners Have Certain Rights"

Issue 01-8, "Determining Whether an Arrangement Contains a Lease"

Issue 00-21, "Revenue Arrangements With Multiple Deliverables"

SEC C&DI Topic

Non-GAAP Financial Measures

SEC Regulation G

"Conditions for Use of Non-GAAP Financial Measures"

SEC Regulation S-K

Item 10(e), "General; Use of Non-GAAP Financial Measures in Commission Filings"

Item 601(b)(10), "Exhibits; Description of Exhibits; Material Contracts"

SEC Regulation S-X

Rule 3-05, "Financial Statements of Businesses Acquired or to Be Acquired"

Rule 4-08(h), "General Notes to Financial Statements; Income Tax Expense"

Article 11, "Pro Forma Financial Information"

SEC Staff Accounting Bulletin

SAB Topic 1.M, "Financial Statements; Materiality"

SAB Topic 13, "Revenue Recognition"

SAB Topic 13.A.4, "Revenue Recognition; Selected Revenue Recognition Issues; Fixed or Determinable Sales Price"

International Standards

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

IAS 17, *Leases*

Appendix B — Abbreviations

Abbreviation	Description
AFS	available for sale
AICPA	American Institute of Certified Public Accountants
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
APIC	additional paid-in capital
ASC	FASB Accounting Standards Codification
ASU	FASB Accounting Standards Update
BOLI	bank-owned life insurance
C&DI	SEC Compliance and Disclosure Interpretation
CECL	current expected credit loss
CODM	chief operating decision maker
COLI	corporate-owned life insurance
CRO	contract research organization
DCP	disclosure control procedure
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
EITF	Emerging Issues Task Force
EPS	earnings per share
EU	European Union
FAQ	frequently asked question
FASB	Financial Accounting Standards Board
FDA	Food and Drug Administration
FIFO	first in, first out

Abbreviation	Description
FIN	FASB Interpretation Number (superseded)
FOB	free on board
GAAP	generally accepted accounting principles
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IPR&D	in-process research and development
LIFO	last in, first out
LLC	limited liability company
LP	limited partnership
M&A	merger and acquisition
MD&A	Management's Discussion and Analysis
MDET	medical device excise tax
MSL	medical science liaison
NDA	new drug application
OCI	other comprehensive income
OEM	original equipment manufacturer
PCAOB	Public Company Accounting Oversight Board
PCD asset	purchased financial asset with credit deterioration
PMA	premarket approval
PTRS	probability of technical and regulatory success
Q&A	question and answer

Abbreviation	Description
R&D	research and development
REMS	risk evaluation and mitigation strategy
ROU	right of use
SAB	SEC Staff Accounting Bulletin
SAC	subjective acceleration clause
SEC	Securities and Exchange Commission
TRG	transition resource group
VIE	variable interest entity
WAC	wholesaler acquisition cost

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