Revenue Recognition

Introduction
The sections below discuss revenue recognition topics that are particularly relevant to life sciences entities under both of the following:

- The guidance in ASU 2014-09, as amended (the “new revenue standard,” codified primarily in ASC 606).
- Legacy guidance (specifically, ASC 605 and SAB Topic 13).

For public business entities (PBEs) as well as certain not-for-profit entities (NFPs) and employee benefit plans, the new revenue standard is effective for annual reporting periods beginning after December 15, 2017. For all other entities, the new revenue standard is effective for annual reporting periods beginning after December 15, 2018. Early adoption is permitted as applicable.

New Revenue Standard (Codified Primarily in ASC 606)

Background
In May 2014, the FASB and IASB issued their final standard on revenue from contracts with customers. The standard, issued as ASU 2014-09 by the FASB and as IFRS 15 by the IASB, outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance.

Upon issuing the new revenue standard, the FASB and IASB formed a joint revenue transition resource group (TRG). The purpose of the TRG is not to issue guidance but instead to seek and provide feedback on potential issues related to implementation of the new revenue standard. By analyzing and discussing potential implementation issues, the TRG has helped the boards determine whether to take additional action, such as providing clarification or issuing other guidance.

Largely as a result of feedback provided by the TRG after the issuance of the initial ASU, the FASB issued the following ASUs to amend and clarify the guidance in the new revenue standard:

- ASU 2015-14, Deferral of the Effective Date.
- ASU 2016-08, Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net).
- ASU 2016-10, Identifying Performance Obligations and Licensing.
- ASU 2016-12, Narrow-Scope Improvements and Practical Expedients.
- ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers.
- ASU 2017-05, Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets.
In addition to the above ASUs, life sciences entities should be aware of recent pronouncements and activities of the SEC staff, including the following:

- **SEC staff announcement at the July 20, 2017, EITF meeting** — The SEC staff provided significant relief to registrants that are required to include financial statements or financial information of other reporting entities in their SEC filings. Specifically, as reported in the minutes of the EITF meeting, the SEC staff announced that it would not object to elections by certain PBEs to use the non-PBE effective dates for the sole purpose of adopting the FASB's new standards on revenue (ASC 606) and leases (ASC 842). The staff announcement makes clear that the ability to use non-PBE effective dates for adopting the new revenue and leases standards is limited to the subset of PBEs “that otherwise would not meet the definition of a public business entity except for a requirement to include or the inclusion of its financial statements or financial information in another entity's filing with the SEC” (referred to herein as “specified PBEs”).

While the staff announcement is written in the context of specified PBEs, the principal beneficiaries of the relief will be SEC filers that include financial statements or financial information prepared by specified PBEs in their own filings, for example, under the following SEC Regulation S-X rules:

- Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired.”
- Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons.”
- Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired.”
- Rule 4-08(g), “Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons.”

See Deloitte’s July 20, 2017, Heads Up for more information about the definition of a PBE.

- **The August 18, 2017, release of SAB 116** — SAB 116 provides that SAB Topic 13 will no longer be applicable when a registrant adopts ASC 606 since ASC 606 “eliminates the need for [SAB] Topic 13.” In addition, SAB 116 modifies SAB Topic 11.A to clarify that “revenues from operating-differential subsidies presented under a revenue caption should be presented separately from revenue from contracts with customers accounted for under [ASC] 606.” For more information about SAB 116, see Deloitte’s August 22, 2017, journal entry.

ASU 2014-09 states that the core principle of the new revenue recognition guidance is that an “entity shall recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.” The ASU indicates that an entity should perform the following five steps in recognizing revenue:

- “Identify the contract(s) with a customer” (step 1).
- “Identify the performance obligations in the contract” (step 2).
- “Determine the transaction price” (step 3).
- “Allocate the transaction price to the performance obligations in the contract” (step 4).
- “Recognize revenue when (or as) the entity satisfies a performance obligation” (step 5).
As a result of the guidance in ASU 2014-09, as amended, entities will need to comprehensively reassess their current revenue accounting policies and determine whether changes are necessary. In addition, ASU 2014-09 requires significantly expanded disclosures about revenue recognition, including both quantitative and qualitative information about (1) the amount, timing, and uncertainty of revenue (and related cash flows) from contracts with customers; (2) the judgment, and changes in judgment, exercised in the application of the new revenue standard; and (3) the assets recognized from costs to obtain or fulfill a contract with a customer.

The sections below discuss some of the key accounting considerations under the new revenue standard for life sciences entities. For more detailed information about the new revenue standard, see Deloitte's A Roadmap to Applying the New Revenue Recognition Standard (the “Revenue Roadmap”) and its TRG Snapshot series. See also Deloitte's February 22, 2017, Heads Up for a discussion of certain of the disclosure requirements that may be particularly challenging for life sciences entities to implement and Deloitte's May 9, 2017, Heads Up for considerations related to a company's internal control over financial reporting in connection with its adoption of the new revenue standard.

Scope
The new revenue standard applies to all contracts with customers as defined in the standard except those that are within the scope of other topics in the FASB Accounting Standards Codification. For example, the new revenue standard does not apply to contracts within the scope of ASC 840 and ASC 842 (leases). In addition, certain provisions in the new revenue standard also apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity’s ordinary activities (e.g., intangible assets such as intellectual property (IP) rights). Such provisions include guidance on recognition (including determining the existence of a contract and control principles) and measurement.

Some of the more common questions that life sciences entities have faced when considering the scope of the new revenue standard are discussed below.

Applicability of the New Revenue Standard to the Parties of a Collaborative Arrangement

Question
Does the new revenue standard apply to the parties of a collaborative arrangement?

Answer
It depends. The new revenue standard applies to all contracts with customers. ASC 606-10-15-3 defines a customer as “a party that has contracted with an entity to obtain goods or services that are an output of the entity’s ordinary activities in exchange for consideration.” However, that provision also notes that a “counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a [collaborative] arrangement) rather than to obtain the output of the entity’s ordinary activities.”
The Basis for Conclusions of ASU 2014-09 also explains that the relationship between a customer and a vendor varies from industry to industry and that companies will therefore have to consider their own facts and circumstances to determine who is a customer in an arrangement. For many contracts, this will not be very difficult to determine; however, paragraph BC54 of ASU 2014-09 provides examples of arrangements in which the facts and circumstances would have to be assessed, including “[c]ollaborative research and development efforts between biotechnology and pharmaceutical entities or similar arrangements in the aerospace and defense, technology, and healthcare industries, or in higher education.”

The example below illustrates how an entity would determine whether an arrangement is a collaborative arrangement and, if so, whether it should be accounted for under ASC 606.

**Example**

Biotech B and Pharma P enter into an agreement to research, develop, and commercialize drug X. Biotech B will perform the R&D, and Pharma P will commercialize the drug. Both parties agree to participate equally in all activities that result from the research, development, and commercialization. The reporting entity concludes that a collaborative arrangement exists because both parties are active participants and have agreed to share in the risks and rewards.

Despite this conclusion, however, there still could be an entity-customer relationship as a result of other contracts between the two companies. If such a relationship exists, those parts of the contract that are related to the entity-customer relationship should be accounted for under ASC 606.

**Connecting the Dots**

ASC 606 does not change the guidance in ASC 808 on the income statement presentation, classification, and disclosures applicable to collaborative arrangements within the scope of the new revenue standard. It is important to understand that a contract could be within the scope of both the new revenue standard and the guidance on collaborative agreements, as indicated in paragraph BC55 of ASU 2014-09:

> The Boards noted that a contract with a collaborator or a partner (for example, a joint arrangement as defined in IFRS 11, Joint Arrangements, or a collaborative arrangement within the scope of Topic 808, Collaborative Arrangements) also could be within the scope of Topic 606 if that collaborator or partner meets the definition of a customer for some or all of the terms of the arrangement.

This is important because companies may have to assess the scope of both ASC 606 and ASC 808 for these types of arrangements. In addition, the Basis for Conclusions of ASU 2014-09 does not preclude companies from analogizing to the guidance in ASC 606 when accounting for collaborative arrangement transactions within the scope of ASC 808.

**Considerations Relevant to Applying Revenue Literature by Analogy**

Collaborative arrangements involving life sciences entities frequently involve activities such as R&D, regulatory activities, manufacturing, distribution, sales and marketing activities, and general and administrative tasks. Often, a governance structure (e.g., a joint steering committee) is also established to facilitate decision-making during the terms of the endeavor. Upon entering into a collaborative arrangement, the partners frequently exchange up-front license fees and agree to subsequent payments based on the achievement of milestones during drug development, as well as future royalties and profit/loss-sharing provisions.
In determining the accounting for these arrangements, many entities currently apply revenue recognition guidance by analogy. These entities often conclude that the collaborative activities do not represent separate deliverables (i.e., they conclude that there is one “unit of accounting,” which represents the right to actively participate in the collaborative arrangement over its term and to share in the profits or losses from the underlying drug endeavor). Notwithstanding this conclusion, in practice the up-front proceeds that the parties exchange upon entering into the collaborative arrangement are frequently accounted for separately from the consideration subsequently exchanged as the parties fulfill their responsibilities and share costs. This accounting is often referred to as a “multiple attribution for a single unit of accounting” method of recognizing arrangement consideration in earnings.

**Question**
What considerations are relevant to entities that apply revenue literature by analogy when adopting the new revenue standard?

**Answer**
ASC 606-10-25-32 states that an “entity shall apply a single method of measuring progress for each performance obligation satisfied over time, and the entity shall apply that method consistently to similar performance obligations and in similar circumstances.” This “single attribution” method differs from the multiple attribution method currently used in practice by many life sciences entities in accounting for their collaborative arrangements. As noted in the On the Horizon section below, the FASB recently commenced a project aimed at making targeted improvements to clarify when transactions between partners in a collaborative arrangement are within the scope of the new revenue standard. However, it is currently unclear to what extent, if any, the FASB project will address the single attribution requirement of the new revenue standard with respect to collaborative arrangements. In the interim, entities are encouraged to discuss these accounting arrangements with their accounting advisers.

**Free Placement of Medical Device Consumables in Exchange for the Customer’s Commitment to a Minimum Purchase**
The new revenue standard does not apply to contracts with customers (or portions thereof) that fall within the scope of other applicable guidance, such as ASC 840 and ASC 842 (leases). Some entities may need to obtain an understanding of the new leases standard as well as their lease contracts to determine the full scope of customer arrangements that fall within the scope of ASC 606. For example, to facilitate the sale and use of medical device consumables, medical device companies may place equipment for free at the customer’s location for a multiyear term. In exchange for the placed equipment, the customer is typically required to commit to a minimum purchase of consumable products during that term.

**Question**
What considerations are relevant to the determination of how to apply the new revenue standard to this type of arrangement?
**Answer**

To determine how the arrangement should be accounted for under the new revenue standard, the reporting entity should first consider whether the placement of equipment meets the definition of a lease under ASC 840 (current U.S. GAAP) and ASC 842 (future U.S. GAAP). If the arrangement includes elements that meet the definition of a lease, the lease-related elements of the arrangement would need to be accounted for under the lease accounting literature. If the arrangement does not meet the definition of a lease and no other literature is directly applicable, the new revenue standard would be applied to the entire arrangement. For additional considerations related to the new leases standard, refer to the **Leases** section of this publication.

**Sale or Outlicensing of IP Rights in Exchange for Future Milestone Payments, Royalties, or Both**

Life sciences entities frequently sell or outlicense IP rights (e.g., in-process R&D (IPR&D) or developed product rights) in exchange for future milestone payments, royalties, or both (i.e., variable consideration).

**Question**

What considerations are relevant to the determination of the accounting model to apply to these types of arrangements?

**Answer**

Transactions involving the transfer of IP rights require significant judgment. Accounting for these transactions depends on whether the transfer involves (1) the sale of IP rights, (2) the license of IP rights, or (3) the sale of IP rights together with other inputs and processes that meet the definition of a business:

- **Sale of IP rights** — The new revenue standard's provisions apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity's ordinary activities (e.g., intangible assets such as IP rights). The following example in ASC 610-20-55-17 through 55-19 illustrates how an entity would account for the sale of a nonfinancial asset in exchange for variable consideration:

  **ASC 610-20**

<table>
<thead>
<tr>
<th>Example 3 — Sale of a Nonfinancial Asset for Variable Consideration</th>
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<tbody>
<tr>
<td><strong>55-17</strong> An entity sells (that is, does not out license) the rights to in-process research and development that it recently acquired in a business combination and measured at fair value of $50 million in accordance with Topic 805 on business combinations. The entity concludes that the transferred in-process research and development is not a business. The buyer of the in-process research and development agrees to pay a nonrefundable amount of $5 million at inception plus 2 percent of sales of any products derived from the in-process research and development over the next 20 years. The entity concludes that the sale of in-process research and development is not a good or service that is an output of the entity's ordinary activities.</td>
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</tbody>
</table>
ASC 610-20 (continued)

55-18 Topic 350 on goodwill and other intangibles requires the entity to apply the guidance in this Subtopic to determine the amount and timing of income to be recognized. Therefore, the entity applies the derecognition guidance in this Subtopic as follows:

   a. The entity concludes that it does not have a controlling financial interest in the buyer.

   b. The entity concludes that the contract meets the criteria in paragraph 606-10-25-1.

   c. The entity also concludes that on the basis of the guidance in paragraph 606-10-25-30, it has transferred control of the in-process research and development asset to the buyer. This is because the buyer can use the in-process research and development's records, patents, and supporting documentation to develop potential products and the entity has relinquished all substantive rights to the in-process research and development asset.

   d. In estimating the consideration received, the entity applies the guidance in Topic 606 on determining the transaction price, including estimating and constraining variable consideration. The entity estimates that the amount of consideration that it will receive from the sales-based royalty is $100 million over the 20-year royalty period. However, the entity cannot assert that it is probable that recognizing all of the estimated variable consideration in other income would not result in a significant reversal of that consideration. The entity reaches this conclusion on the basis of its assessment of factors in paragraph 606-10-32-12. In particular, the entity is aware that the variable consideration is highly susceptible to the actions and judgments of third parties, because it is based on the buyer completing the in-process research and development asset, obtaining regulatory approval for the output of the in-process research and development asset, and marketing and selling the output. For the same reasons, the entity also concludes that it could not include any amount, even a minimum amount, in the estimate of the consideration. Consequently, the entity concludes that the estimate of the consideration to be used in the calculation of the gain or loss upon the derecognition of the in-process research and development asset is limited to the $5 million fixed upfront payment.

55-19 At inception of the contract, the entity recognizes a net loss of $45 million ($5 million of consideration, less the in-process research and development asset of $50 million). The entity reassesses the transaction price at each reporting period to determine whether it is probable that a significant reversal would not occur from recognizing the estimate as other income and, if so, recognizes that amount as other income in accordance with paragraphs 606-10-32-14 and 606-10-32-42 through 32-45.

- **License of IP rights** — In contrast to the accounting for a sale of IP, for a licensing transaction in which consideration is tied to the subsequent sale or usage of IP, the new revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, the entity would wait until the subsequent sale or usage occurs to determine the amount of revenue to recognize.

- **Sale of IP rights together with other inputs and processes that meet the definition of a business** — ASC 610-20 does not amend or supersede guidance that addresses how to determine the gain or loss on the derecognition of a subsidiary or a group of assets that meets the definition of a business. Gains or losses associated with such a transaction will continue to be determined in accordance with ASC 810-10-40. As discussed in the Q&A Seller's (Parent's) Accounting for Contingent Consideration Upon Deconsolidation of a Subsidiary or Derecognition of a Group of Assets That Is a Business, entities should establish an accounting policy for the initial and subsequent measurement of this type of arrangement.
Identify the Contract (Step 1)

For contracts within the scope of ASC 606, the first step of the new revenue standard is to determine whether a contract exists, for accounting purposes, between an entity and its customer.

**ASC 606-10**

<table>
<thead>
<tr>
<th>25-1 An entity shall account for a contract with a customer that is within the scope of this Topic only when all of the following criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. The parties to the contract have approved the contract (in writing, orally, or in accordance with other customary business practices) and are committed to perform their respective obligations.</td>
</tr>
<tr>
<td>b. The entity can identify each party’s rights regarding the goods or services to be transferred.</td>
</tr>
<tr>
<td>c. The entity can identify the payment terms for the goods or services to be transferred.</td>
</tr>
<tr>
<td>d. The contract has commercial substance (that is, the risk, timing, or amount of the entity’s future cash flows is expected to change as a result of the contract).</td>
</tr>
<tr>
<td>e. It is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer (see paragraphs 606-10-55-3A through 55-3C). In evaluating whether collectibility of an amount of consideration is probable, an entity shall consider only the customer’s ability and intention to pay that amount of consideration when it is due. The amount of consideration to which the entity will be entitled may be less than the price stated in the contract if the consideration is variable because the entity may offer the customer a price concession (see paragraph 606-10-32-7).</td>
</tr>
</tbody>
</table>

A contract does not have to be written to meet the criteria for revenue recognition. However, it does need to create enforceable rights and obligations.

Some of the more common questions that life sciences entities have faced when considering step 1 of the new revenue standard are discussed below.

### Identifying the Parties That Are Relevant to the Determination of Whether a Contract Exists

**Question**

Given the number of entities involved in the distribution channel/pricing chain within the life sciences industry, questions have arisen about which parties are relevant to the determination of whether a contract exists. For example, for a pharmaceutical company, does a contract for purposes of step 1 include only the contract between the pharmaceutical company and the wholesaler, or does it also include “downstream” contracts with others in the pricing chain to whom discounts or rebates may be provided?
Answer
An important step in the new revenue standard is determining when an agreement with a customer represents a contract for accounting purposes. The criteria in ASC 606-10-25-1 that need to be in place to establish that a contract exists are intended to demonstrate that there is a valid and genuine transaction between an entity and its customer and that the parties to the contract have enforceable rights and obligations that will have true economic consequences. For a traditional pharmaceutical company, the wholesaler to which the company’s products are shipped would generally represent the customer. In these circumstances, other parties that may be involved in the distribution/pricing chain do not represent the company’s customers and therefore are irrelevant to the determination of whether a contract exists for accounting purposes. However, life sciences entities should keep in mind that any pricing adjustments (e.g., rebates, chargebacks) that are payable as result of these arrangements may represent variable consideration that is required to be estimated and potentially constrained under step 3 of the model.

Whether the Transaction Price Must Be Fixed or Determinable

Question
Does the criterion in ASC 606-10-25-1 that the “entity can identify the payment terms for the goods or services to be transferred” (emphasis added) require that the transaction price be fixed or determinable as required under legacy guidance?

Answer
No. A contract must include payment terms for each of the promised goods and services in an arrangement for an entity to determine the transaction price. The payment terms do not need to be fixed, but the contract must contain enough information to allow an entity to reasonably estimate the consideration to which it will be entitled for transferring the goods and services to the customer.

Example
Pharmaceutical Company X has received approval from a foreign government to sell drug A to government hospitals in advance of obtaining full market authorization in the jurisdiction. During this “early access period” in which X’s application for full marketing authorization is being evaluated by the foreign government, X will be paid a preliminary price by the government hospitals. During this same period, X will be negotiating with the foreign government the final price to be paid to X. Upon obtaining full marketing authorization and completing pricing negotiations, X will be required to rebate to the foreign government the difference between the preliminary price and the final price.

Under legacy guidance, the lack of a fixed or determinable final selling price would generally preclude the recognition of revenue until the final price is determined. Under the new revenue standard, however, payment terms may have been established between X and the government hospitals because X can (1) determine, for example, when payment is due and that the consideration is variable and (2) reasonably estimate the amount of consideration to which it will ultimately be entitled on the basis of the ongoing negotiations with the foreign government.
Price Concessions

Question

How do price concessions (variable consideration) affect the timing of revenue recognition under ASC 606-10-25-1, which requires that “[i]t is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer” (emphasis added)?

Answer

As part of determining whether a valid and genuine contract exists, an entity is required to evaluate whether it is probable that the entity will collect substantially all of the consideration to which it is entitled under the contract. However, the consideration to which an entity is ultimately entitled may be less than the price stated in the contract because the customer is offered a price concession. Price concessions are a form of variable consideration and need to be analyzed when the transaction price is being determined (as part of step 3 of the new revenue model). However, as part of step 1, an entity would evaluate whether it is probable that the entity will collect the consideration to which it will be entitled for providing goods or services to a customer after considering any price concessions. This evaluation requires aspects of step 3 to be performed in conjunction with step 1. Differentiating between credit risk (i.e., the risk of collecting less consideration than the amount the entity legitimately expected to collect from the customer) and price concessions (i.e., entering into a contract with a customer with the expectation of accepting less than the contractual amount of consideration in exchange for goods or services) may be difficult. Entities will need to use significant judgment in determining whether they have provided an implicit price concession or have accepted a customer’s credit risk. This is particularly true of entities in highly regulated industries, such as health care and consumer energy, which may be required by law to provide certain goods and services to their customers regardless of the customers’ ability to pay. Because of the nature of these arrangements, entities will need to evaluate all of the relevant facts and circumstances of their arrangements to determine whether they have provided implicit price concessions or whether the anticipated receipt of less than the total contractual consideration represents credit risk.

Example 2 in ASC 606-10-55-99 through 55-101, which is reproduced below, illustrates how a life sciences entity would evaluate implicit price concessions when assessing whether the collectibility criterion is met.

<table>
<thead>
<tr>
<th>ASC 606-10</th>
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<tbody>
<tr>
<td><strong>Example 2 — Consideration Is Not the Stated Price — Implicit Price Concession</strong></td>
</tr>
<tr>
<td>55-99 An entity sells 1,000 units of a prescription drug to a customer for promised consideration of $1 million. This is the entity’s first sale to a customer in a new region, which is experiencing significant economic difficulty. Thus, the entity expects that it will not be able to collect from the customer the full amount of the promised consideration. Despite the possibility of not collecting the full amount, the entity expects the region’s economy to recover over the next two to three years and determines that a relationship with the customer could help it to forge relationships with other potential customers in the region.</td>
</tr>
</tbody>
</table>
When assessing whether the criterion in paragraph 606-10-25-1(e) is met, the entity also considers paragraphs 606-10-32-2 and 606-10-32-7(b). Based on the assessment of the facts and circumstances, the entity determines that it expects to provide a price concession and accept a lower amount of consideration from the customer. Accordingly, the entity concludes that the transaction price is not $1 million and, therefore, the promised consideration is variable. The entity estimates the variable consideration and determines that it expects to be entitled to $400,000.

The entity considers the customer’s ability and intention to pay the consideration and concludes that even though the region is experiencing economic difficulty it is probable that it will collect $400,000 from the customer. Consequently, the entity concludes that the criterion in paragraph 606-10-25-1(e) is met based on an estimate of variable consideration of $400,000. In addition, based on an evaluation of the contract terms and other facts and circumstances, the entity concludes that the other criteria in paragraph 606-10-25-1 are also met. Consequently, the entity accounts for the contract with the customer in accordance with the guidance in this Topic.

**Contract Term**

Determining the term of the contract is an important step in the revenue recognition process since the contract term could affect the identification of promises under the contract as well as the transaction price. ASC 606 provides guidance on determining the contract duration, including the effect of termination clauses and contract renewals. The contract term is determined on the basis of the period over which the parties to the contract have present enforceable rights and obligations.

Some contracts with customers may have no fixed duration and can be terminated or modified by either party at any time. Other contracts may automatically renew on a periodic basis that is specified in the contract. An entity shall apply the guidance in this Topic to the duration of the contract (that is, the contractual period) in which the parties to the contract have present enforceable rights and obligations. In evaluating the criterion in paragraph 606-10-25-1(e), an entity shall assess the collectibility of the consideration promised in a contract for the goods or services that will be transferred to the customer rather than assessing the collectibility of the consideration promised in the contract for all of the promised goods or services (see paragraphs 606-10-55-3A through 55-3C). However, if an entity determines that all of the criteria in paragraph 606-10-25-1 are met, the remainder of the guidance in this Topic shall be applied to all of the promised goods or services in the contract.

In the life sciences industry, contract research organizations (CROs) typically enter into long-term contracts with their customers to perform clinical trial management services. Because of the high failure rates in the clinical development process, it is customary in the CRO industry to provide the customer the right to terminate the contract with the CRO without cause. The customer is often required to give a specified notice of termination (e.g., 30 days) and to compensate the CRO for all work performed through the date of termination, as well as for any noncancelable arrangements the CRO has entered into and any wind-down activities required to close the study. In addition, some contracts may include a termination fee for early cancellation of a study.
Considerations for Evaluating the Impact of Termination Provisions on the Determination of the Contract Term

Question
What factors should an entity (e.g., a CRO) consider when evaluating the impact of termination provisions on the determination of the contract term?

Answer
The TRG noted that the duration of a contract is predicated on the contract's enforceable rights and obligations. Accordingly, regardless of whether one or both parties have the right to terminate the contract, an entity would need to evaluate the nature of the termination provisions, including whether they are substantive. For example, an entity would assess factors such as (1) whether the terminating party is required to pay compensation, (2) the amount of such compensation, and (3) the reason for the compensation (i.e., whether the compensation is in addition to amounts due for goods and services already delivered). Substantive termination penalties suggest that the parties' rights and obligations extend for the duration of the contract term.

TRG members acknowledged that the determination of whether a termination provision is substantive will require judgment and would be evaluated both quantitatively and qualitatively. Some offered that data about the frequency of contract terminations may be useful in such a determination (i.e., a high frequency of payments made to terminate contracts may suggest that the termination provision is not substantive).

Further, TRG members generally agreed that a contract's accounting term could be less than the contract's stated term if termination provisions are not substantive. That is, a 12-month stated contract term could, in effect, be a month-to-month contract if the contract could be terminated and the termination penalties are not substantive. An entity will need to carefully consider the effect of nonsubstantive termination provisions and clauses on the timing and amount of revenue to be recognized.

In practice, CROs often experience a low frequency of payments made to terminate contracts, which may suggest that the termination provisions are substantive. A substantive termination penalty is evidence of enforceable rights and obligations on the part of both parties throughout the period in which the substantive termination penalty applies.

Connecting the Dots
Some contracts include promises to provide goods or services upon the occurrence of a contingent event. For example, a contract may require an entity to provide additional CRO services in future phases of development if clinical trials in the current stage of development are successful. Similarly, a contract may require a company to provide commercial manufacturing services for a product if and when the customer obtains regulatory approval. Contingent promises may be viewed as similar to customer options that an entity evaluates to determine whether a material right exists (see the discussion of material rights in Identify the Performance Obligations (Step 2) below). If a material right does not exist, the initial contract term excludes the period in which the contingent promise would be delivered.
Contract Modifications

ASC 606-10

25-10 A contract modification is a change in the scope or price (or both) of a contract that is approved by
the parties to the contract. In some industries and jurisdictions, a contract modification may be described as
a change order, a variation, or an amendment. A contract modification exists when the parties to a contract
approve a modification that either creates new or changes existing enforceable rights and obligations of the
parties to the contract. A contract modification could be approved in writing, by oral agreement, or implied
by customary business practices. If the parties to the contract have not approved a contract modification, an
entity shall continue to apply the guidance in this Topic to the existing contract until the contract modification is
approved.

25-11 A contract modification may exist even though the parties to the contract have a dispute about the scope
or price (or both) of the modification or the parties have approved a change in the scope of the contract but
have not yet determined the corresponding change in price. In determining whether the rights and obligations
that are created or changed by a modification are enforceable, an entity shall consider all relevant facts
and circumstances including the terms of the contract and other evidence. If the parties to a contract have
approved a change in the scope of the contract but have not yet determined the corresponding change in
price, an entity shall estimate the change to the transaction price arising from the modification in accordance
with paragraphs 606-10-32-5 through 32-9 on estimating variable consideration and paragraphs 606-10-32-11
through 32-13 on constraining estimates of variable consideration.

Contract modifications can frequently happen in the normal course of business. Any time an entity
and its customer agree to change what the entity promises to deliver or the amount of consideration
the customer will pay, there is a contract modification. Therefore, the first step in the identification of a
contract modification is to assess whether, for a contract accounted for under ASC 606, there has been
a change in the contract’s scope or price, or both. The second step is to determine whether the parties
to the contract have agreed upon the change. As defined above, contract modifications must be agreed
to by both parties (written, orally, or through customary business practices). That is, both parties must
agree to change the enforceable rights and obligations of the contract.

As noted above, CROs in the life sciences industry often enter into long-term contracts with their
customers to perform clinical trial management services. Changes in the scope of these contracts is
common in the industry.

If a CRO and its customer agree upon a change to a contract and the change qualifies as a contract
modification under ASC 606-10-25-10 and 25-11, the CRO will be required to evaluate the appropriate
accounting for that contract modification.

Considerations for Determining How to Account for a Modification Involving a Change in the Contract’s Scope or Price

Question

When a change in a contract’s scope, price, or both occurs, what factors should an entity (e.g., a
CRO) consider in determining how to account for that modification?
Answer

The entity must assess the goods and services and their selling price. Depending on whether those goods and services are distinct or sold at the stand-alone selling price, a modification can be accounted for as:

- A separate contract (see ASC 606-10-25-12).
- One of the following (if the modification is not accounted for as a separate contract):
  - A termination of the old contract and the creation of a new contract (see ASC 606-10-25-13(a)).
  - A cumulative catch-up adjustment to the original contract (see ASC 606-10-25-13(b)).
  - A combination of the items described in ASC 606-10-25-13(a) and (b), in a way that faithfully reflects the economics of the transaction (see ASC 606-10-25-13(c)).

Contract Modification Accounted for as a Separate Contract

<table>
<thead>
<tr>
<th>ASC 606-10</th>
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<tbody>
<tr>
<td><strong>25-12</strong></td>
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<tr>
<td>An entity shall account for a contract modification as a separate contract if both of the following conditions are present:</td>
</tr>
<tr>
<td>a. The scope of the contract increases because of the addition of promised goods or services that are distinct (in accordance with paragraphs 606-10-25-18 through 25-22).</td>
</tr>
<tr>
<td>b. The price of the contract increases by an amount of consideration that reflects the entity’s standalone selling prices of the additional promised goods or services and any appropriate adjustments to that price to reflect the circumstances of the particular contract. For example, an entity may adjust the standalone selling price of an additional good or service for a discount that the customer receives, because it is not necessary for the entity to incur the selling-related costs that it would incur when selling a similar good or service to a new customer.</td>
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With the overall goal of accurately representing the economics of the transaction in mind, the FASB and IASB decided that there is no economic difference between (1) the modification of an existing contract with a customer to include additional distinct goods or services at their representative stand-alone selling price and (2) a completely new contract entered into by the two parties. Therefore, a contract modification should be accounted for as a separate contract only if there are additional distinct goods or services promised to a customer as a result of the modification. However, for the contract modification to be accounted for as a separate contract, those goods or services must be in exchange for consideration that represents the stand-alone selling price of the additional distinct promised goods or services.

Because a modification to a CRO contract often may not add “distinct” goods or services at a price that reflects the stand-alone selling price of those goods or services, such a modification is generally not accounted for as a new contract separate from the original contract. Instead, as further discussed below, this type of modification is typically (1) viewed as part of a single performance obligation that is partially satisfied on the date of the modification and (2) accounted for as if it were part of the original contract.

A modification that results in a decrease in scope cannot be accounted for as a separate contract because the criterion in ASC 606-10-25-12(a) specifying an increase in the scope of the contract is not met.
Contract Modification Not Accounted for as a Separate Contract

ASC 606-10

25-13 If a contract modification is not accounted for as a separate contract in accordance with paragraph 606-10-25-12, an entity shall account for the promised goods or services not yet transferred at the date of the contract modification (that is, the remaining promised goods or services) in whichever of the following ways is applicable:

a. An entity shall account for the contract modification as if it were a termination of the existing contract, and the creation of a new contract, if the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification. The amount of consideration to be allocated to the remaining performance obligations (or to the remaining distinct goods or services in a single performance obligation identified in accordance with paragraph 606-10-25-14(b)) is the sum of:
   1. The consideration promised by the customer (including amounts already received from the customer) that was included in the estimate of the transaction price and that had not been recognized as revenue and
   2. The consideration promised as part of the contract modification.

b. An entity shall account for the contract modification as if it were a part of the existing contract if the remaining goods or services are not distinct and, therefore, form part of a single performance obligation that is partially satisfied at the date of the contract modification. The effect that the contract modification has on the transaction price, and on the entity's measure of progress toward complete satisfaction of the performance obligation, is recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) at the date of the contract modification (that is, the adjustment to revenue is made on a cumulative catch-up basis).

c. If the remaining goods or services are a combination of items (a) and (b), then the entity shall account for the effects of the modification on the unsatisfied (including partially unsatisfied) performance obligations in the modified contract in a manner that is consistent with the objectives of this paragraph.

If a contract modification does not meet the requirements to be accounted for as a separate contract, an entity would have to determine how to account for a blended contract that now includes one or both of the following:

- An original agreement plus or minus some other goods or services.
- A change in the amount of consideration due under the modified arrangement.

The determination of which model to use depends on whether the remaining goods or services (the originally promised items and the newly promised items) are distinct from the goods and services already provided under the contract.

If the remaining goods or services are distinct from those already provided under the original arrangement, the entity would in effect establish a “new” contract that includes only those remaining goods and services. In this situation, the entity would allocate to the remaining performance obligations in the contract (1) consideration from the original contract that has not yet been recognized as revenue and (2) any additional consideration from the modification.
In contrast, if the contract modification results in remaining goods and services that are not distinct, the entity should account for the modification as though the additional goods and services were an addition to an incomplete performance obligation. This may be the case when a CRO's contract with a customer contains one performance obligation and the parties modify the terms to change the scope of the services provided. In this instance, a measure of progress, such as costs incurred, would typically be used to recognize the revenue. For example, suppose that just before the modification, the entity's performance was 30 percent complete. After the modification, the entity may determine that its performance is only 25 percent complete (or 35 percent complete). As a result, an updated revenue figure is calculated on the basis of the revised percentage, and the entity would record a cumulative catch-up adjustment.

The FASB and IASB recognized that there may be contracts in which some performance obligations include remaining goods or services that are distinct from those already provided under the original arrangement, while other performance obligations include remaining goods and services that are not (i.e., a change in scope of a partially satisfied performance obligation). In those circumstances, the boards decided that it may be appropriate, as described in ASC 606-10-25-13(c), to apply each of the models to parts of a contract. An entity would do so by accounting for the performance obligations that are not yet fully satisfied (i.e., including those that are partially satisfied). No change would be made to revenue recognized for fully satisfied performance obligations.

**Identify the Performance Obligations (Step 2)**

Step 2 is one of the most critical steps in the new revenue framework since it establishes the unit of account for revenue recognition. This step requires an entity to identify what it has promised to the customer. The entity then determines whether a promise or multiple promises represent one or more performance obligations to the customer. To accomplish this, the entity should determine whether the promises in the contract are distinct. ASC 606-10-25-19 notes that “a good or service that is promised to a customer is distinct if both of the following criteria are met”:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct).
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).

Further, ASC 606-10-25-22 states that “[i]f a promised good or service is not distinct, an entity shall combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. In some cases, that would result in the entity accounting for all the goods or services promised in a contract as a single performance obligation.”

The new revenue standard's guidance on determining whether a customer can benefit from a good or service on its own or together with other readily available resources is generally consistent with the legacy guidance in ASC 605-25 on determining whether a good or service has stand-alone value. However, the requirement that a good or service be “separately identifiable from other promises in the contract” is a new concept under which entities must further evaluate a good or service for separability.
To help an entity assess whether its promises to transfer goods or services to the customer are separately identifiable, ASC 606-10-25-21 identifies the following factors “that indicate that two or more promises to transfer goods or services to a customer are not separately identifiable” (emphasis added):

- The entity provides a significant service of integrating [the] goods or services with other goods or services promised in the contract into a bundle of goods or services that represent the combined output or outputs for which the customer has contracted.
- One or more of the goods or services significantly modifies or customizes, or are significantly modified or customized by, one or more of the other goods or services promised in the contract.
- The goods or services are highly interdependent or highly interrelated. In other words, each of the goods or services is significantly affected by one or more of the other goods or services in the contract. For example, in some cases, two or more goods or services are significantly affected by each other because the entity would not be able to fulfill its promise by transferring each of the goods or services independently.

In the life sciences industry, CROs often provide multiple services for their pharmaceutical and biotechnology customers. For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results. These services are generally considered to represent a single performance obligation because they are not “separately identifiable.”

Some of the more common questions that life sciences entities have faced when considering step 2 of the new revenue standard are discussed below.

License of IP Bundled With Other Services

Arrangements involving the license of IP and other services (e.g., contract R&D services or contract manufacturing services) are common in the life sciences industry. For example, biotechnology companies frequently enter into license and development arrangements with pharmaceutical companies, and contract manufacturers frequently enter into license and supply arrangements with pharmaceutical companies.

Question

With respect to identifying performance obligations, how does the analysis of such arrangements under ASC 606 compare with that under legacy guidance?

Answer

Life sciences entities that grant a license bundled with other services (e.g., contract R&D services or contract manufacturing services) may need to use significant judgment when determining whether the goods or services in a contract (1) are capable of being distinct (have stand-alone value) and (2) are not highly interdependent or highly interrelated and do not significantly modify or customize one another (are separately identifiable). While the analysis of whether the goods or services are capable of being distinct is generally consistent with the analysis of “standalone value” under legacy guidance, the “separately identifiable” concept is new and may require entities to account for a bundle of goods or services, which may represent separate units of accounting under legacy guidance, as a single performance obligation (unit of accounting).
Considering Whether It Is Feasible for Another Vendor to Perform the Same Services

Question

In the evaluation of whether a license of IP and contract R&D services (or contract manufacturing services) are separate performance obligations, how should an entity consider whether it is feasible for another vendor to provide the same services?

Answer

ASC 606-10-55-367 through 55-372A of the new revenue standard, relevant parts of which are reproduced below, include two fact patterns that illustrate how the determination of whether it is feasible for another life sciences entity to provide the same services affects the analysis of whether the “capable of being distinct” criterion is met.

ASC 606-10

Example 56 — Identifying a Distinct License

55-367 An entity, a pharmaceutical company, licenses to a customer its patent rights to an approved drug compound for 10 years and also promises to manufacture the drug for the customer for 5 years, while the customer develops its own manufacturing capability. The drug is a mature product; therefore, there is no expectation that the entity will undertake activities to change the drug (for example, to alter its chemical composition). There are no other promised goods or services in the contract.

Case A — License Is Not Distinct

55-368 In this case, no other entity can manufacture this drug while the customer learns the manufacturing process and builds its own manufacturing capability because of the highly specialized nature of the manufacturing process. As a result, the license cannot be purchased separately from the manufacturing service.

55-369 The entity assesses the goods and services promised to the customer to determine which goods and services are distinct in accordance with paragraph 606-10-25-19. The entity determines that the customer cannot benefit from the license without the manufacturing service; therefore, the criterion in paragraph 606-10-25-19(a) is not met. Consequently, the license and the manufacturing service are not distinct, and the entity accounts for the license and the manufacturing service as a single performance obligation.

Case B — License Is Distinct

55-371 In this case, the manufacturing process used to produce the drug is not unique or specialized, and several other entities also can manufacture the drug for the customer.

55-372 The entity assesses the goods and services promised to the customer to determine which goods and services are distinct, and it concludes that the criteria in paragraph 606-10-25-19 are met for each of the license and the manufacturing service. The entity concludes that the criterion in paragraph 606-10-25-19(a) is met because the customer can benefit from the license together with readily available resources other than the entity's manufacturing service (that is, because there are other entities that can provide the manufacturing service) and can benefit from the manufacturing service together with the license transferred to the customer at the start of the contract.
ASC 606-10 (continued)

The entity also concludes that its promises to grant the license and to provide the manufacturing service are separately identifiable (that is, the criterion in paragraph 606-10-25-19(b) is met). The entity concludes that the license and the manufacturing service are not inputs to a combined item in this contract on the basis of the principle and the factors in paragraph 606-10-25-21. In reaching this conclusion, the entity considers that the customer could separately purchase the license without significantly affecting its ability to benefit from the license. Neither the license nor the manufacturing service is significantly modified or customized by the other, and the entity is not providing a significant service of integrating those items into a combined output. The entity further considers that the license and the manufacturing service are not highly interdependent or highly interrelated because the entity would be able to fulfill its promise to transfer the license independent of fulfilling its promise to subsequently manufacture the drug for the customer. Similarly, the entity would be able to manufacture the drug for the customer even if the customer had previously obtained the license and initially utilized a different manufacturer. Thus, although the manufacturing service necessarily depends on the license in this contract (that is, the entity would not contract for the manufacturing service without the customer having obtained the license), the license and the manufacturing service do not significantly affect each other. Consequently, the entity concludes that its promises to grant the license and to provide the manufacturing service are distinct and that there are two performance obligations:

a. License of patent rights
b. Manufacturing service.

Connecting the Dots

Determining whether R&D services or manufacturing services are separately identifiable from licenses can require significant judgment. While “bright lines” do not exist, the stage of development may be relevant to the determination of whether R&D services are expected to significantly modify or customize the IP (e.g., R&D services for early-stage IP frequently involve activities that lead to changes in a drug compound’s formulation, dosing levels, and manufacturing process, whereas R&D services for later-stage IP may only involve validating the drug’s efficacy).

Similarly, if the manufacturing of active pharmaceutical ingredient (API) is performed to support R&D services, the manufacturing and R&D may not be distinct because the company cannot fulfill its promise to perform R&D independently from its promise to manufacture API. Conversely, manufacturing of an approved product may be more likely to be “distinct” if another party could perform the services.

Contractual Requirement That the Entity’s Customer Must Use the Entity’s Services

Question

In the evaluation of whether a license of IP and contract R&D services (or contract manufacturing services) are separate performance obligations, how should an entity consider a contractual requirement that the entity’s customer must use the entity’s services?
**Answer**

A contractual requirement that the entity's customer must use the entity's R&D services (or manufacturing services) does not change the evaluation of whether the promised goods and services are distinct. In accordance with ASC 606-10-55-150F, “[t]his is because the contractual requirement to use the entity’s . . . services does not change the characteristics of the goods or services themselves, nor does it change the entity's promises to the customer.” Specifically, ASC 606-10-55-64 notes the following:

Contractual provisions that explicitly or implicitly require an entity to transfer control of additional goods or services to a customer (for example, by requiring the entity to transfer control of additional rights to use or rights to access intellectual property that the customer does not already control) should be distinguished from contractual provisions that explicitly or implicitly define the attributes of a single promised license (for example, restrictions of time, geographical region, or use). Attributes of a promised license define the scope of a customer’s right to use or right to access the entity’s intellectual property and, therefore, do not define whether the entity satisfies its performance obligation at a point in time or over time and do not create an obligation for the entity to transfer any additional rights to use or access its intellectual property.

Consequently, if the license and the services are otherwise capable of being distinct and separately identifiable, the license and the services would be accounted for as two performance obligations.

**Determining Whether Other Promises in the Life Sciences Industry Are Separate Performance Obligations**

The illustrative examples in ASC 606 provide certain facts used to support a determination of whether a promised good or service is distinct and therefore a separate performance obligation. However, some facts may vary between examples while the conclusions are consistent. For instance, in Example 11, Case C (ASC 606-10-55-150A through 55-150D), one of the facts provided to support the conclusion that the equipment and installation services represent two performance obligations is that others can provide the installation services. However, in Example 11, Case E (ASC 606-10-55-150G through 55-150K), one of the facts provided to support the conclusion that the equipment and specialized consumables are also two performance obligations is that the specialized consumables are not available from other entities.

**Question**

If a good or service (e.g., installation service) is unavailable from alternative providers or available from only a limited number of alternative providers, is an entity precluded from considering the good or service to be a separate performance obligation?

**Answer**

No. The unavailability of a good or service from alternative providers is a factor for an entity to consider in evaluating whether the good or service is distinct (and therefore a separate performance obligation), but that factor is not individually determinative (as noted in the examples cited above). Entities need to use judgment in evaluating whether a promise to provide a good or service, in addition to other goods or services, is capable of being distinct and is distinct within the context of the contract (i.e., separately identifiable) in accordance with
ASC 606-10-25-19. In making that determination, an entity may focus on why a good or service is or is not available from other providers, especially when evaluating the following factors in ASC 606-10-25-21 to conclude on whether the good or service is separately identifiable:

- Whether there is a significant service of integrating goods or services.
- Whether the good or service significantly modifies or customizes another good or service.
- Whether the good or service is highly dependent on or highly interrelated with any other goods or services.

For example, if an entity sells medical device equipment and provides installation of that equipment, the determination of whether the installation services are available from another entity would be a factor to be considered in the evaluation of whether the installation is distinct within the context of the contract, but that factor alone would not be determinative. It is important for the reporting entity to consider why the installation is unavailable from (or available from only a limited number of) alternative providers to determine whether the installation is separately identifiable in accordance with ASC 606-10-25-21. For example, if the entity has a standard installation process that does not significantly customize or modify the equipment for the entity’s customer, the entity may conclude that the installation is separately identifiable regardless of whether there are no other installation providers or only a limited number of such providers. However, installation services that are unique and significantly modify or customize the equipment for the customer may suggest that the services are not separately identifiable and therefore are not distinct within the context of the contract.

**Connecting the Dots**

In the life sciences industry, manufacturing facilities and processes are frequently required to be approved by regulators (e.g., the FDA). The absence of alternative facilities with regulatory approval to manufacture a particular product can affect the “distinct” analysis for arrangements involving a license of IP and manufacturing services.

Similarly, biotechnology companies that enter into revenue arrangements with pharmaceutical companies are frequently required by contract to participate in a joint steering committee in addition to licensing a drug candidate and performing R&D services. Although the obligation to participate in a joint steering committee could be determined to be a promised service, it may not represent a “distinct” service unless, for example, other parties could perform the service and the service does not involve a significant integration of other goods and services in the arrangement.

**Evaluating Whether a Promised Good or Service Is Immaterial in the Context of the Contract**

In April 2016, the FASB issued ASU 2016-10, which states that an entity “is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer.” This guidance should not be applied to a customer option to acquire additional goods and services that provides a customer with a material right in accordance with ASC 606-10-55-41 through 55-45.
**Question**

How should an entity evaluate whether a promised good or service is immaterial in the context of the contract?

**Answer**

ASU 2016-10 added ASC 606-10-25-16A and 25-16B, which provide the following guidance on immaterial promised goods or services:

<table>
<thead>
<tr>
<th>ASC 606-10</th>
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<tbody>
<tr>
<td><strong>25-16A</strong> An entity is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer. If the revenue related to a performance obligation that includes goods or services that are immaterial in the context of the contract is recognized before those immaterial goods or services are transferred to the customer, then the related costs to transfer those goods or services shall be accrued.</td>
</tr>
<tr>
<td><strong>25-16B</strong> An entity shall not apply the guidance in paragraph 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right, in accordance with paragraphs 606-10-55-41 through 55-45.</td>
</tr>
</tbody>
</table>

In light of the wording in ASU 2016-10, stakeholders have asked about the framework an entity should use to identify a potential good or service that is immaterial in the context of the contract. The following have been considered, both of which we think are relevant to the assessment of whether a good or service is immaterial in the context of the contract:

- An entity may conclude that a potential good or service is immaterial in the context of the contract if the estimated stand-alone selling price of the potential good or service is immaterial (quantitatively) compared with the total consideration in the contract (i.e., the amount that would be allocated to such good or service is immaterial in the context of the contract).

- An entity may conclude that a potential good or service is immaterial in the context of the contract if it determines that the customer does not consider the potential good or service to be material to the contract (i.e., the entity would evaluate qualitative factors, including the customer's perspective, in determining whether a potential good or service is immaterial in the context of the contract).

For example, a medical device company might offer basic training or education services for equipment that it sells to a hospital. The value of this type of service may be immaterial (quantitatively) compared with the total consideration in the contract. Further, the basic training or education may not be a service that the customer considers to be material to the contract.

In addition, we think that when an entity performs an assessment to identify immaterial promised goods or services, it should also consider the guidance in ASU 2016-10 on customer options (i.e., potential material rights) as well as the SEC staff's view of "material" as discussed in SAB Topic 1.M.
Connecting the Dots

As noted above, an entity should not apply the guidance in ASC 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right. For example, a life sciences company may have a practice of providing customers with the ability to purchase 12 weeks of treatment at list price with an option to purchase an additional 12 weeks of treatment at a significantly discounted price if it is determined that the patient is benefiting from the treatment and additional treatment will be helpful. This type of discount on future treatments based on the efficacy of a drug during the initial treatment period may represent a material right. Similarly, arrangements that include the delivery of free drugs after a contractually defined purchase volume has been achieved may include a material right. Options that are deemed to represent material rights — and, therefore, a performance obligation — would result in a deferral of revenue associated with that performance obligation, as discussed below.

Customer Options for Additional Goods or Services (Material Rights)

An entity’s contract with a customer may give the customer a choice of whether to purchase additional goods or services; such a choice is typically referred to as an option for additional goods or services. Entities are required to identify options for additional goods or services because in certain circumstances, such options can lead to performance obligations. As explained in paragraph BC386 of ASU 2014-09, the FASB and IASB realized that it could be difficult to differentiate between (1) an option for additional goods or services that was paid for by the customer and (2) a marketing or promotional offer for which the customer did not pay. The first type of option for additional goods or services would be identified as a performance obligation to which consideration must be allocated in accordance with step 4 of the new revenue standard.

To help entities determine whether an option for additional goods or services is a performance obligation, the boards included the concept of a material right in the new revenue standard. If an entity determines that an option for additional goods and services is a material right, the option should be considered a performance obligation. However, an entity will need to use judgment to determine whether a material right exists.

The guidance in the new revenue standard describes a material right as an option that provides the customer an incremental discount beyond the discounts that are typically given. This concept of a material right stems from software revenue guidance under legacy U.S. GAAP in ASC 985-605, which provides that a deliverable in a contract should be accounted for separately if it is discounted by a significant and incremental amount with respect to both (1) that contract and (2) other similar contracts. However, a material right under the new guidance is slightly different in that the new revenue standard does not require the material right to be significant and incremental in relation to other discounts within the same contract.

When an option is identified as providing a customer with a material right, the option is identified as a performance obligation. A portion of the transaction price is then allocated to the option and recognized when (or as) (1) the future goods or services related to the option are provided or (2) the option expires.
Whether the Assessment for Determining That a Contract Option Does or Does Not Provide a Material Right Is Only Quantitative

Question
Is the assessment of whether an option provides a customer with a material right only a quantitative assessment?

Answer
No. When determining whether a contract option provides a material right, entities should consider not only the quantitative significance of the option (i.e., the quantitative value of the benefit) but also previous and future transactions with the customer as well as qualitative factors. Specifically, qualitative features such as whether the rights accumulate (e.g., loyalty points) are likely to provide a qualitative benefit that may give rise to a material right.

Paragraph BC87 of ASU 2014-09 indicates that an entity should consider its customer’s valid expectations when identifying promised goods or services. A customer’s perspective on what constitutes a material right might consider qualitative factors (e.g., whether the right accumulates). Therefore, a numeric threshold alone might not determine whether a material right is provided by a customer option in a contract.

Refer to Examples 49, 50, 51, and 52 in ASC 606-10-55-336 through 55-356 for examples of how an entity would determine whether an option provides a customer with a material right.

The TRG discussed this issue in October 2014; a summary of the TRG’s discussion is available in TRG Agenda Paper 11. For additional information and Deloitte's summary, see Appendixes D and E of Deloitte's Revenue Roadmap.

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 and annual increases to a maximum of 75 percent by 2020 in their Medicare prescription drug coverage.

Recognizing Discounts Related to the Medicare Coverage Gap

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. Before the adoption of ASC 606, an entity makes a policy election between two acceptable methods:

- **“Specific identification” (or “point-of-sale”) model** — An entity may apply the specific identification (or point-of-sale) model by estimating which prescription drug sales are attributable to individuals expected to be in the Medicare coverage gap and recognizing the related discount as a reduction of revenue for those sales. Under this model, the discount provided to an 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 estimates when the coverage gap payment would be triggered on the basis of its product portfolio and sales volumes and records that estimate in the initial quarter that is affected.

- **“Spread” (or “effective rate”) model** — Under the spread (or effective rate) model, an entity 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 an individual is in the Medicare coverage gap is considered to be 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 the discounts provided are attributable to all respective Medicare revenues for the year. Under this method, an entity 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 using either the specific identification model or the spread model for the discounts associated with sales attributed to the Medicare coverage gap should apply the method consistently.

We believe that under ASC 606, these same methods are generally supportable as follows:

- **Specific identification approach** — Under this approach, each individual patient purchase is a separate contract and cannot be combined with future “expected” but optional purchases. Accordingly, the consideration due and payable for each individual purchase is attributable to that individual sale. Coverage gap subsidies are viewed as a form of variable consideration attributable to individual sales of products to specific customers in accordance with ASC 606-10-32-6. As a result, the estimate of variable consideration specific to each individual transaction is recorded at the point of sale. The accounting outcome of this approach is generally consistent with that of the specific identification method described above. In a manner similar to the accounting for any form of variable consideration, an entity would estimate the variability (i.e., the occurrence or nonoccurrence of a future coverage gap discount in accordance with ASC 606-10-32-8) and apply the constraint guidance (ASC 606-10-32-11 and 32-12) before recognizing revenue when control of a purchased pharmaceutical drug is transferred into the distribution channel.
• **Material right approach** — Coverage gap subsidies constitute a material right in accordance with ASC 606-10-55-42. In effect, entities have entered into contractual arrangements with the U.S. government on behalf of Medicare-eligible patients in which the entities offer significant discounts on future purchases through the Medicare channel (i.e., all sales with Medicare-eligible patients throughout the year are “linked”). Under this approach, entities allocate a portion of the transaction price between current sales and the material right, which represents the discount to be provided on future sales to any Medicare-eligible patient within the coverage gap, and recognize the value of the material right in revenue when the coverage gap subsidies are used. This approach is inappropriate if rebates are expected to be made early in the year (as is the case for certain high-priced drugs) because it would be inappropriate to record a contract asset for what otherwise represents optional purchases.

**Shipping and Handling Activities**

Shipping and handling activities are often provided by life sciences entities as part of a revenue arrangement.

### Considerations for Evaluating Shipping Terms and Determining the Accounting for Shipping and Handling Activities

**Question**

What considerations are relevant to the evaluation of shipping terms and the determination of how to account for shipping and handling activities performed by a vendor?

**Answer**

It is important to understand the shipping terms of an arrangement to determine when control of the good transfers to the customer. This is because the shipping terms often trigger some of the key control indicators (e.g., transfer of title and present right to payment). Therefore, a careful evaluation of shipping terms in a manner similar to their evaluation under legacy guidance is critical to the assessment of transfer of control. Common shipping terms include “free on board” (FOB) shipping point (title transfers to the customer at the entity’s shipping dock) and FOB destination (title transfers to the customer at the customer’s location).

Under legacy guidance, an entity applies a risks-and-rewards model that requires a careful evaluation of the entity’s involvement during the period of shipment in FOB shipping point fact patterns. That is, when the entity replaces lost or damaged products during shipping even though the shipping terms are FOB shipping point, it is often inappropriate under legacy guidance to recognize revenue upon shipment because the risks and rewards of ownership did not pass to the customer at the shipping point. Such practice should be reevaluated under the new revenue standard’s control-based model. While the fact that the entity has the significant risks and rewards of ownership is an indicator of control, that indicator may be overcome by the other indicators of control. As a result, it may be appropriate to recognize revenue upon shipment when the terms are FOB shipping point regardless of whether the entity retains the risks associated with loss or damage of the products during shipment.
When FOB shipping point fact patterns are reassessed and control is determined to transfer upon shipment, the seller should consider whether the risk of loss or damage that it assumed during shipping gives rise to another performance obligation (a distinct service-type obligation) that needs to be accounted for separately in accordance with the new revenue standard. For example, such risk may represent another performance obligation if goods are frequently lost or damaged during shipping.

Further, entities should consider the practical expedient under U.S. GAAP (ASC 606-10-25-18B, added by ASU 2016-10) that allows entities the option to treat shipping and handling activities that occur after control of the good transfers to the customer as fulfillment activities. Entities that elect to use this practical expedient would not need to account for the shipping and handling as a separate performance obligation. Instead, when the practical expedient is elected and revenue for the related good is recognized before the shipping and handling activities occur, the entity should accrue the costs of the shipping and handling activities at the time control of the related good is transferred to the customer (i.e., at the time of sale).

ASU 2016-10 also explains that shipping and handling activities performed before control of a product is transferred do not constitute a promised service to the customer in the contract (i.e., they represent fulfillment costs).

**Determine the Transaction Price (Step 3)**

In step 3 of the new revenue standard, an entity determines the “transaction price,” which, as stated in ASC 606-10-32-2, represents “the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both.” Because the transaction price is an expected amount, estimates are inherently required. When determining the transaction price, an entity is required under ASC 606-10-32-3 to “consider the effects of all of the following”:

- “Variable consideration.”
- “Constraining estimates of variable consideration.”
- “The existence of a significant financing component in the contract.”
- “Noncash consideration.”
- “Consideration payable to a customer.”

The effects of these elements are particularly relevant to life sciences entities, as explained in the Q&As below.

**Variable Consideration**

**Examples of Variable Consideration**

**Question**

What are examples of variable consideration in the life sciences industry?
**Answer**

ASC 606-10-32-6 explains that variable consideration may arise “because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items” and that the promised consideration can vary “if an entity’s entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event” (e.g., when “a product [is] sold with a right of return or a fixed amount is promised as a performance bonus on achievement of a specified milestone.” In the life sciences industry, common forms of variable consideration include returns, chargebacks, rebates, cash and volume-based discounts, promotions, shelf stock adjustments, and other adjustments to revenue, as well as royalties, development-based milestones, and sales-based milestones.

**Methods of Estimating Variable Consideration**

**Question**

Which methods should a life sciences entity use to estimate variable consideration?

**Answer**

Regardless of the form of variability or its complexity, once variable consideration is identified, an entity is required under ASC 606-10-32-8 to estimate the amount of variable consideration to determine the transaction price in a contract with a customer by using either the “expected value” method or the “most likely amount” method, “depending on which method the entity expects to better predict the amount of consideration to which it will be entitled.” As ASC 606-10-32-8 explains, the expected value is “the sum of probability-weighted amounts in a range of possible consideration amounts. An expected value may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics.” ASC 606-10-32-8 further states that the most likely amount is “the single most likely amount in a range of possible consideration amounts (that is, the single most likely outcome of the contract).”

In the life sciences industry, it may be appropriate for an entity to estimate development and sales-based milestones by using the most likely amount method since the achievement of a milestone has only two possible outcomes (an entity either achieves the milestone or does not achieve it). Other forms of variable consideration may be estimated under the expected value method. For example, estimates of returns under the expected value method may take into account factors such as the following:

- The period in which returns can occur.
- Experiences with products (or the inability to apply such experiences to current products).
- Availability of information about product levels and the age of the product in the distribution channel.
- Predictability of market conditions and competition (e.g., competitive entry of a similar or generic product).
- The current stage in the product life cycle (i.e., initial product launch vs. end/maturity of product life).
- Historical, current, and projected demand.
In addition to the factors listed above, the following factors may be relevant to the development of estimates of variable consideration in the form of chargebacks and rebates under the expected value method:

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

In applying the expected value method to these types of estimates, life sciences entities are not necessarily expected to develop complex modeling techniques to identify all possible outcomes of variable consideration. Although we think that it is appropriate for an entity to be pragmatic in deriving an estimate by using one of the required methods, we do not think that it is appropriate to use a method described as management’s best estimate as either the most likely amount or the expected value of variable consideration. Consequently, entities are encouraged to evaluate their current estimation approaches for variable consideration and document the basis for any conclusion that these approaches align with the estimation methods of ASC 606.

**Price Protection Arrangements**

Life sciences entities sometimes enter into price protection arrangements, under which wholesalers are reimbursed for any difference between the current sales price and the lowest price offered during a subsequently specified period (e.g., one year).

**Question**

How should an entity consider the guidance on variable consideration when accounting for price protection arrangements?

**Answer**

Under legacy guidance, the amount of revenue recognized is generally limited to the amount that is not contingent on a future event (i.e., the sales price is “fixed or determinable” and no longer variable). Accordingly, a price protection arrangement under legacy guidance may result in a conclusion that the selling price was not fixed or determinable on the date of sale because of the possibility of future price concessions. Consequently, revenue in such an arrangement may not be recognized until reliable estimates can be established or the product is sold through to the end user (i.e., on a sell-through basis).

Under the new revenue standard, an entity must include some or all of an estimate of variable (or contingent) consideration in the transaction price (which is the amount to be allocated to each unit of account and recognized as revenue) when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of revenue in subsequent periods. In price protection arrangements, the transaction price would therefore include an estimate of expected price protection determined under either the expected value method or the most likely outcome method (i.e., whichever method the entity expects to better predict the amount of consideration to which it will be entitled), with revenue recognized when control transfers to the distributor.
Connecting the Dots

Instead of providing a retroactive discount, price protection arrangements may be structured to provide a discount on future purchases if a life sciences company sells its products to another customer at a lower price during a subsequently specified period. In these circumstances, the entity should consider whether the price protection arrangement conveys a material right to buy products at a lower price in the future. If a material right is determined to exist, this would represent a separate performance obligation to which a portion of the transaction price would need to be allocated. If a material right does not exist (e.g., because the discount applies only to future purchases and is not based on the volume of past purchases), there would be no impact on current sales, and future sales would be recognized at the discounted prices.

New Product Launches With a Right of Return

Question

How should an entity consider the guidance on variable consideration when accounting for new product launches that include a right of return?

Answer

Under legacy guidance, life sciences entities are required to make a reasonable estimate regarding future returns to recognize revenue upon shipment of the product. ASC 605-15-25-3 indicates that the ability to make such an estimate depends on many factors and identifies a number of factors that may impair this ability (see the Ability to Reasonably Estimate Returns section below for additional discussion).

Under the new revenue standard, a sale with a right of return is not a separate variable consideration model or — as some have thought about it under legacy guidance — a “failed” sale model. Rather, the uncertainty associated with whether a product may be returned is treated, for measurement purposes, consistently with the uncertainty associated with other variable consideration. That is, under ASC 606-10-55-25:

An entity should . . . determine the amount of consideration to which the entity expects to be entitled (that is, excluding the products expected to be returned). For any amounts received (or receivable) for which an entity does not expect to be entitled, the entity should not recognize revenue when it transfers products to customers but should recognize those amounts received (or receivable) as a refund liability. Subsequently, at the end of each reporting period, the entity should update its assessment of amounts for which it expects to be entitled in exchange for the transferred products and make a corresponding change to the transaction price and, therefore, in the amount of revenue recognized.

Pay-for-Performance Arrangements

Pay-for-performance arrangements are becoming increasingly more common in the life sciences industry. In these arrangements, a drug manufacturer could be required to reimburse all or a portion of the amounts originally received upon sale of the drug if, after a defined treatment period, a patient does not exhibit certain predetermined objective criteria.

Question

How should an entity consider the guidance on variable consideration in the new revenue standard when accounting for pay-for-performance arrangements?
Answer

Under legacy guidance, life sciences entities are required to reasonably estimate future adjustments to the amounts billed for the product. If the vendor does not have a company-specific historical basis to estimate refunds, revenue is generally deferred until the close of the predetermined contingency period.

Under the new revenue standard, however, pay-for-performance arrangements represent another form of variable consideration. In a manner similar to the accounting in the examples above, a life sciences entity with these types of arrangements must include some or all of an estimate of variable consideration in the transaction price when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of cumulative revenue in subsequent periods.

Retroactive Payback Provisions

In certain countries, companies are required to pay rebates to the country's government health care system if domestic industry sales exceed specified thresholds in a given year. If the threshold is exceeded, the portion of the payback allocated to an individual company is based on that company's current market share (or sales) in relation to the industry as a whole.

Question

How should an entity consider the guidance on variable consideration when accounting for a retroactive payback provision?

Answer

Under the new revenue standard, an entity would account for the retroactive payback provision as a retroactive rebate (i.e., variable consideration) and possibly use the expected value method to estimate it, subject to the constraint.

Volume Rebates

A life sciences entity may offer its customers rebates or discounts on the pricing of products or services once specific volume thresholds have been met. That is, an entity may either retrospectively or prospectively adjust the price of its goods or services once a certain volume threshold has been met.

Question 1

Should an entity account for an offer to retrospectively lower the price per unit (once certain volume thresholds are met) as variable consideration (rather than as a customer option to be evaluated as a potential material right)?

Answer

Yes. A volume rebate or discount that is retrospectively applied should be accounted for as variable consideration under ASC 606. In accordance with ASC 606-10-32-6, which specifically includes discounts and rebates as a form of variable consideration, the “promised consideration also can vary if an entity’s entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event” (emphasis added).
Question 2
Should an entity account for an offer to prospectively lower the price per unit (once certain volume thresholds are met) as variable consideration (rather than as a customer option to be evaluated as a potential material right)?

Answer
No. When a volume rebate or discount is applied prospectively, entities will need to evaluate the facts and circumstances of each contract to determine whether the rebate or discount represents a material right and therefore should be accounted for as a performance obligation. As part of this evaluation, entities would consider whether the offer to the customer is at a price that would reflect the stand-alone selling price for that good or service, in accordance with ASC 606-10-55-43.

Discounts Provided to Group Purchasing Organizations
Life sciences companies frequently enter into agreements with group purchasing organizations (GPOs) to provide discounts to hospitals that are affiliated with the GPOs. Distributors of the life sciences companies’ products then request reimbursement of the discounts provided to the life sciences companies’ hospital customers.

Question
How should a life sciences company account for discounts provided to GPOs?

Answer
In accordance with the new revenue standard, a life sciences company should treat these discounts as variable consideration and possibly use the expected value method to estimate the discounts, subject to the constraint.

In addition to providing these discounts, life sciences companies frequently pay administrative fees to GPOs to fund the expenses of GPO members. To determine the appropriate classification of these administrative fees as a reduction of revenue or as an increase to operating expense, a life sciences company should consider the relationships between the vendor, the GPO, and the GPO member to determine whether the GPO is a customer. For example, the company might consider the GPO to be a customer, and therefore may be required to reflect the fee as a reduction of revenue, if the GPO is a related party of the GPO member or if there is a mechanism to pass through the administrative fee from the GPO to the GPO member.

Connecting the Dots
Similar questions related to income statement classification may arise regarding payments made by life sciences companies to NFPs or other organizations that fund copay assistance programs to defray the cost of high-priced drugs. Specifically, there may be questions about whether these payments represent consideration paid to an indirect customer (e.g., because the contribution funds are ultimately used by patients to purchase the company’s products). While these payments are frequently classified in expense under legacy guidance, life sciences companies are encouraged to evaluate their facts and circumstances to determine whether these payments represent a form of variable consideration under the new revenue standard.
Constraining Estimates of Variable Consideration

Since revenue is one of the most important metrics to users of financial statements, the FASB and IASB and their constituents agreed that estimates of variable consideration are useful only to the extent that an entity is confident that the revenue recognized as a result of those estimates will not be subsequently reversed. Accordingly, as noted in paragraph BC203 of ASU 2014-09, the boards acknowledged that some estimates of variable consideration should not be included in the transaction price if the inherent uncertainty could prevent a faithful depiction of the consideration to which the entity expects to be entitled in exchange for delivering goods or services. Thus, the focus of the boards' deliberations on a mechanism to improve the usefulness of estimates in revenue as a predictor of future performance was to limit subsequent downward adjustments in revenue (i.e., reversals of revenue recognized). The result of those deliberations is what is commonly referred to as the “constraint.”

ASC 606-10-32-11 and 32-12 describe the constraint and provide guidance on how it should be applied:

<table>
<thead>
<tr>
<th>ASC 606-10</th>
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<tbody>
<tr>
<td><strong>32-11</strong> An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 606-10-32-8 only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.</td>
</tr>
<tr>
<td><strong>32-12</strong> In assessing whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur once the uncertainty related to the variable consideration is subsequently resolved, an entity shall consider both the likelihood and the magnitude of the revenue reversal. Factors that could increase the likelihood or the magnitude of a revenue reversal include, but are not limited to, any of the following:</td>
</tr>
<tr>
<td>a. The amount of consideration is highly susceptible to factors outside the entity's influence. Those factors may include volatility in a market, the judgment or actions of third parties, weather conditions, and a high risk of obsolescence of the promised good or service.</td>
</tr>
<tr>
<td>b. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.</td>
</tr>
<tr>
<td>c. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.</td>
</tr>
<tr>
<td>d. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.</td>
</tr>
<tr>
<td>e. The contract has a large number and broad range of possible consideration amounts.</td>
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</table>

Importantly, the constraint does not apply to sales- or usage-based royalties derived from the licensing of IP; rather, consideration from such royalties is only recognized as revenue at the later of when the performance obligation is satisfied or when the uncertainty is resolved (e.g., when subsequent sales or usage occurs). See the Licensing section below for additional discussion.
Factors for Determining Whether to Constrain Estimates of Variable Consideration

Question
What factors may be relevant to a life sciences entity’s determination of whether to constrain its estimates of variable consideration?

Answer
Inherent in ASC 606-10-32-12 are three key aspects of the assessment necessary for an entity to determine whether an estimate of variable consideration in a contract with a customer should be constrained in an entity’s transaction price:

- The likelihood of a reversal in the cumulative amount of revenue recognized (i.e., a qualitative aspect).
- The magnitude (or significance) of the potential reversal in the cumulative amount of revenue recognized (i.e., a quantitative aspect).
- The threshold that triggers a constrained estimate (i.e., the use of “probable”).

The determination of whether to constrain estimates of variable consideration may require significant judgment depending on the nature of the revenue stream being estimated. For example, it may be unnecessary for an entity to constrain revenue on the sale of established pharmaceutical products to wholesalers since variable consideration (e.g., rebates, discounts) may not be highly susceptible to factors outside the entity’s influence (e.g., volatility in a market, the judgment or actions of third parties, a high risk of obsolescence), the uncertainty about the amount of consideration may be resolved in a shorter period, the entity may have significant experience with similar types of contracts or with contracts that have predictive value, and the range of price concessions is narrow.

In contrast, it may be necessary to constrain a significant portion of revenue on the sale of IPR&D, a nonfinancial asset, in exchange for future development milestones and royalties and sales-based milestones since the likelihood of reversal in the cumulative amount of revenue recognized could be high and the magnitude of the potential reversal could be significant. The uncertainty associated with revenue related to such a transaction arises from a number of factors:

- Before regulatory approval, uncertainty may arise from potential delays with clinical trials, success of competitor trials, or an inability to obtain regulatory approvals.
- After regulatory approval, uncertainty may arise from product safety concerns, manufacturing issues, potential product recalls, the introduction of competitor products, or possible sales and distribution channel issues.
- Both before and after regulatory approval, the amount of consideration to be received may be highly susceptible to factors outside the entity’s influence because success is predicated on the efforts of the party to which the IPR&D was sold.
Although the guidance on constraining estimates of variable consideration is intended to avoid significant downward adjustments in revenue after it has been recognized, we generally do not think that it would be appropriate to constrain 100 percent of an estimate of variable consideration. That is, we do not think that the factors in ASC 606-10-32-12 could be so significant that an estimate of variable consideration should be entirely constrained from the transaction price. This concept is different from a $0 estimate of variable consideration. A 100 percent constraint on an estimate of variable consideration that is not $0, however, would generally go against the measurement principle of ASC 606, which is to include in the transaction price the amount to which an entity expects to be entitled for its performance so that the entity can provide financial statement users a better prediction of future revenues.

While the above is a general interpretation, there are exceptions in the new revenue standard that may allow for a 100 percent constraint on an estimate of variable consideration. Example 25 in ASC 606-10-55 discusses an exception in which market-based factors are a significant driver of variability in the transaction price. Also, in paragraph BC415 of ASU 2014-09, the boards discuss their rationale for providing an exception for sales- or usage-based royalties in a license of IP.

**Connecting the Dots**

Milestone payments that are due upon regulatory approval are inherently based on factors outside the entity’s control. As a result, life sciences companies that use a most likely method to estimate variable consideration may conclude that the variable consideration associated with a regulatory approval milestone is $0 before regulatory approval. However, there may be certain cases in which a milestone earned upon regulatory approval becomes probable before the approval date. For example, when an authorized generic of an existing branded drug is under FDA review, an entity may determine before the actual approval date that approval is likely to occur. Contrast that with a new drug compound for which there is no competitor on the market. In this case, it may be more difficult to assert probability in advance of the actual approval date. In addition, in determining whether to recognize an approval-based milestone before approval occurs, entities are encouraged to consider how the judgments they make when applying the constraint guidance compare with the judgments they make when determining whether to capitalize “prelaunch inventory” since a probability assessment is required in each instance.¹

¹ While a probability assessment in a constraint analysis may give rise to conclusions similar to those resulting from a probability assessment in a prelaunch inventory analysis, the term “probable” is defined differently in each assessment. For purposes of determining the constraint under the new revenue standard, “probable” is defined in a manner consistent with the ASC 450 definition in that the future event or events are likely to occur. For purposes of assessing whether prelaunch inventory meets the definition of an asset, footnote 18 of FASB Concepts Statement 6 states that “[p]robable is used with its usual general meaning, rather than in a specific accounting or technical sense (such as that in FASB Statement No. 5, Accounting for Contingencies, par. 3), and refers to that which can reasonably be expected or believed on the basis of available evidence or logic but is neither certain nor proved.”
**Significant Financing Components**

In certain contracts with customers, one party may provide a service of financing (either explicitly or implicitly) to the other. Such contracts effectively contain two transactions: one for the delivery of the good or service and another for the benefit of financing (i.e., what is in substance a loan payable or loan receivable). The FASB and IASB decided that an entity should account for both transactions included in a contract with a customer when the benefit of the financing provided is significant. ASC 606-10-32-15 states the following:

In determining the transaction price, an entity shall adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the entity with a significant benefit of financing the transfer of goods or services to the customer. In those circumstances, the contract contains a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract.

In determining the transaction price, an entity adjusts the promised amount of consideration to determine the cash selling price of the good or service to be delivered and reflect the time value of money if the contract has a significant financing component. The direction of the financing component (i.e., whether financing provided to the entity through an advance payment or to the customer through payments in arrears) is irrelevant to the assessment, and as a result of the adjustment to the transaction price, the entity could recognize interest expense or interest income.

However, ASC 606-10-32-18 provides a practical expedient under which an entity does not need to adjust the promised amount of consideration for the effects of a significant financing component “if the entity expects, at contract inception, that the period between when the entity transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less.”

## Factors for Determining Whether a Significant Financing Component Exists

Life sciences entities often receive advance payments for services. For example, payments are often required by CROs in advance of performing clinical trials, or by third-party manufacturers to secure manufacturing capacity.

**Question**

What factors may be relevant for life sciences entities to consider in determining whether there is a significant financing component in a contract with a customer?
**Answer**

Entities must use judgment in determining whether a significant financing component exists. However, ASC 606-10-32-17 notes that a contract with a customer would not have a significant financing component if certain factors exist. The table below describes the factors of greatest relevance to life sciences entities and examples of arrangements in which these factors may apply.

<table>
<thead>
<tr>
<th>Factor (ASC 606-10-32-17)</th>
<th>Example</th>
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<tr>
<td>“A substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the customer or the entity.”</td>
<td>Royalty arrangements, in which variability is provided to confirm the value of goods delivered.</td>
</tr>
<tr>
<td>“The difference between the promised consideration and the cash selling price of the good or service (as described in [ASC] 606-10-32-16) arises for reasons other than the provision of finance to either the customer or the entity, and the difference between those amounts is proportional to the reason for the difference. For example, the payment terms might provide the entity or the customer with protection from the other party failing to adequately complete some or all of its obligations under the contract.”</td>
<td>Customer withholds consideration until the achievement of a certain milestone and to protect against nonperformance. Customer required to pay up front to secure supply of a good.</td>
</tr>
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</table>

**Allocate the Transaction Price to the Performance Obligations (Step 4)**

In step 4 of the new revenue standard, an entity allocates the transaction price to each of the identified performance obligations. For a contract containing more than one performance obligation, the allocation is generally performed on the basis of the relative stand-alone selling price of each distinct good or service.

As discussed in Deloitte’s Revenue Roadmap, there are exceptions that allow an entity to allocate a disproportionate amount of the transaction price to a specific performance obligation. For example, an entity may allocate a discount to a single performance obligation rather than proportionately to all performance obligations if certain factors indicate that the discount is related to a specific performance obligation.
In addition, in arrangements that include a license of IP along with ongoing services (e.g., R&D or manufacturing) that represent distinct performance obligations, an entity is required to allocate the total transaction price between the license and the services. If a history of selling the services or IP separately does not exist, the entity will need to estimate the stand-alone selling price of each performance obligation by using one of the following methods:

- **Adjusted market assessment approach** — Under this method, an entity considers the market in which the good or service is sold and estimates the price that a customer in that market would be willing to pay. In addition, the entity considers a competitor’s pricing for similar goods or services as adjusted for specific factors such as position in the market, expected profit margin, and customer-specific or geography-specific conditions. For example, a life sciences company may need to consider the specific rights associated with the license, the stage of development of the underlying IP, and the projected cash flows over the license period. Regarding the R&D services, prices of similar services offered in the marketplace may be considered.

- **Expected cost plus a margin** — Under this method, an entity estimates the stand-alone selling price by considering the costs incurred to produce the product or service plus an adjustment for the expected margin on the sale. This method may be appropriate for an entity to use when it determines the selling price of R&D or manufacturing services by considering the level of effort necessary to perform the services.

- **Residual approach** — This approach may only be used if the entity sells the same good or service to different customers for a broad range of amounts, making the consideration highly variable, or the entity has not yet established a price for that good or service and the good or service has not previously been sold. Under this method, the entity deducts the estimated stand-alone selling price of other goods and services in the contract from the total transaction price to determine the stand-alone selling price of the remaining goods and services.

In many other respects, the allocation model under the new revenue standard may be similar to the model under legacy guidance, except for the new revenue standard’s elimination of the selling price hierarchy required under legacy guidance. For certain life sciences companies, however, the allocation model under the new revenue standard may result in differences as a result of the elimination of the “contingent cap” concept. Specifically, under legacy guidance, the allocation of arrangement consideration to delivered items is limited to the amount of revenue that is not contingent on the delivery of future items. The new revenue standard does not include this same contingent cap. As a result, the timing of revenue recognition under the new revenue standard may be accelerated as compared with its timing under legacy guidance.

### Example

A medical device company sells infusion pumps and intravenous solutions (consumables). In accordance with the company’s contracts with customers, title to the pumps is transferred to the customer for free when the pumps are sold in conjunction with a minimum commitment for the purchase of consumables. Assume that the pumps and solutions are considered separate performance obligations.

Under legacy guidance, because the consideration to be received for one of the deliverables in the arrangement (i.e., equipment) is contingent on the sale of other deliverables in the arrangement (i.e., consumables), the medical device company would limit recognition of revenue for the delivered element up to the amount of consideration that is not contingent on the future sales. In this case, because the pump is provided to the customer for free and all of the consideration from the arrangement is contingent on the sale of disposables, the company would not recognize revenue when the pump is delivered to the customer. Under the new revenue standard, however, the company would estimate the amount of consideration to which it expects to be entitled and allocate the consideration on a relative stand-alone selling price basis to each separate performance obligation.
Determine When to Recognize Revenue (Step 5)

In a manner consistent with the core principle of the new revenue standard — “an entity shall recognize revenue to depict the transfer of promised goods or services to customers” (emphasis added) — step 5 focuses on recognition (i.e., when it is appropriate to recognize revenue).

The new standard requires an entity first to determine, at contract inception, whether control of a good or service is transferred over time; if so, the entity would recognize the related revenue over time in a manner consistent with the transfer of the good or service over time to the customer. This method is similar to the percentage-of-completion and proportional-performance methods in practice under legacy guidance. If the entity cannot conclude that control is transferred over time, control is considered to be transferred at a point in time. As a result, the entity must determine at what specific point in time to recognize the related revenue. While generally speaking, goods are transferred at a point in time and services are transferred over time, this is not the case in all circumstances. Some of the more common questions that life sciences entities have faced when considering step 5 are described below.

Determining Whether to Recognize Revenue Over Time or at a Point in Time

Question

Contract manufacturing is common in the life sciences industry. Should entities that are delivering goods (e.g., contract manufacturers and other customer manufacturing arrangements) recognize revenue over time or at a particular point in time?

Answer

It depends. Entities should carefully analyze the contractual arrangement in accordance with the three criteria in ASC 606-10-25-27 to determine whether the promise in the contract to construct and transfer goods to the customer is a performance obligation that will be satisfied over time or at a point in time.

If an entity’s obligation to produce a customized product meets one of the criteria in ASC 606-10-25-27 for revenue recognition over time (e.g., the entity’s performance does not create an asset with an alternative use, and the entity has an enforceable right to payment for performance completed to date), revenue related to that product would be recognized as the product is produced, not when the product is delivered to the customer.

For example, an entity that has a contract with an original equipment manufacturer (OEM) to produce a customized part for the OEM’s product would meet the criteria for revenue recognition over time if the customized part has no alternative use other than as a part for the OEM’s product and, as stated in ASC 606-10-25-29, the entity has an enforceable right to payment for performance completed to date “at all times throughout the duration of the contract.” ASC 606-10-25-28 and 25-29 as well as ASC 606-10-55-8 through 55-15 provide detailed guidance on whether an asset has an alternative use to the entity and whether an entity has an enforceable right to payment for performance completed to date. An entity would need to carefully analyze the contractual arrangements and the specific facts and circumstances to determine whether those criteria are met.
If the entity concludes that revenue should be recognized over time, it would then be required to select a method of recognizing revenue over time that most faithfully depicts the entity's performance to date for producing the product. Therefore, contract revenue should be recognized as revenue when the entity performs (i.e., the products are produced) rather than when the products are delivered to the customer.

**Connecting the Dots**

In certain contract manufacturing arrangements of life sciences entities, inventory that is being manufactured has no alternative use (e.g., because the product cannot be redirected to another customer), and the contract terms provide the right to payment for performance completed to date in an amount that approximates the selling price of the work in process (e.g., recovery of the costs incurred plus a reasonable profit margin) if the contract is canceled. In these arrangements, revenue should be recognized over time as inventory is manufactured.

Entities may need to use judgment when evaluating some of these arrangements (e.g., when contracts are silent or unclear about whether a right to payment exists). We believe that when a contract's written terms do not specify the entity's right to payment upon contract termination, an enforceable right to payment is presumed not to exist. However, if the contract with the customer does not specify by its written terms the entity's right to payment upon contract termination and the entity asserts that it has an enforceable right to payment for performance completed to date, we would expect the entity to:

- Support its assertion on the basis of legislation, administrative practice, or legal precedent that confers upon the entity a right to payment for performance to date, as stated in ASC 606-10-55-14(a). This analysis would need to demonstrate that an enforceable right to payment (as defined by ASC 606) exists in the relevant jurisdiction. The fact that the entity would have a basis for making a claim against the counterparty in a court of law would not be sufficient to support the existence of an enforceable right to payment.

- Assess whether relevant legal precedent indicates that similar rights to payment for performance completed to date in similar contracts have no binding legal effect, as stated in ASC 606-10-55-14(b).

**Impact of Shipping Terms on Revenue Recognition Over Time**

**Question**

Do shipping terms in a contract that require a customer to pay only at a specific point in time (e.g., FOB destination) preclude the contract from meeting the criterion in ASC 606-10-25-27(c) for revenue recognition over time (specifically, the enforceable right to payment condition)?

**Answer**

No. The guidance in ASC 606-10-55-12 makes clear that an enforceable right to payment “need not be a present unconditional right to payment” and that an entity may have “an unconditional right to payment only . . . upon complete satisfaction of the performance obligation.” In these circumstances, the guidance states, “an entity should consider whether it would have an enforceable right to demand or retain payment for performance completed to date if the contract were to be terminated before completion for reasons other than the entity’s failure to perform as promised” (emphasis added).
When a contract’s shipping terms require an entity’s customer to pay only at a specific point in time (e.g., FOB destination), the possibility that the entity will not be paid if the goods are lost in shipment would represent “the entity’s failure to perform as promised” and should be disregarded in the entity's assessment of whether the performance obligation meets the criterion in ASC 606-10-25-27(c) for revenue recognition over time (i.e., when an entity is assessing whether it has an enforceable right to payment, it should presume that it will perform as promised and that the goods will be delivered). Accordingly, the conclusion that the entity has an enforceable right to payment is not precluded when the contract’s payment terms require payment only at specific points in the production or delivery process. Those payment terms may be overruled by contractual rights that give the entity an enforceable right to demand or retain payment (if the entity performs as promised). Therefore, the fact that the customer would not be required to pay for the goods if they were lost in transit would not, by itself, preclude the contract from meeting the criterion in ASC 606-10-25-27(c) for revenue recognition over time.

Selecting a Measure of Progress Toward Complete Satisfaction of a Performance Obligation

When a performance obligation is satisfied over time, an entity must select a measure of progress (e.g., time elapsed, labor hours, costs incurred) to depict its progress toward complete satisfaction of that obligation.

In accordance with ASC 606-10-25-33, appropriate methods of measuring progress include:

- **Output methods** — ASC 606-10-55-17 states that output methods “recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract.” These methods include “surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units produced or units delivered.”

- **Input methods** — ASC 606-10-55-20 states that input methods “recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (for example, resources consumed, labor hours expended, costs incurred, time elapsed, or machine hours used) relative to the total expected inputs to the satisfaction of that performance obligation.”

In discussing the selection of a measure of progress, paragraph BC164 of ASU 2014-09 states:

The [FASB and IASB] decided that, conceptually, an output measure is the most faithful depiction of an entity's performance because it directly measures the value of the goods or services transferred to the customer. However, the Boards observed that it would be appropriate for an entity to use an input method if that method would be less costly and would provide a reasonable proxy for measuring progress.

Many CROs recognized revenue over time by using either input or output methods under legacy guidance.
**Question**

Does the statement in paragraph BC164 of ASU 2014-09 mean that it is preferable for an entity to use an output method when measuring progress toward complete satisfaction of a performance obligation?

**Answer**

No. As stated in paragraph BC159 of ASU 2014-09, an entity does not have a free choice in selecting an appropriate method of measuring progress toward complete satisfaction of a performance obligation but should exercise judgment in identifying a method that fulfills the stated objective in ASC 606-10-25-31 of depicting an entity’s performance in transferring control of goods or services promised to a customer (i.e., the satisfaction of the performance obligation).

Neither an input method nor an output method is preferred since each has benefits and disadvantages that will make it more or less appropriate to the facts and circumstances of each contract. While an output method is, as stated in paragraph BC164 of ASU 2014-09, conceptually preferable in a general sense, an appropriate measure of output will not always be directly observable; and sometimes, an apparent measure of output will not in fact provide an appropriate measure of an entity’s performance. Information needed to apply an input method is more likely to be available to an entity without undue cost, but care should be taken to ensure that any measure of an entity’s inputs used is reflective of the transfer of control of goods or services to the customer.

Considerations that may be relevant to the selection of a measure of progress include the following:

- An output method would not provide a faithful depiction of the entity’s performance if the output selected fails to measure some of the goods or services transferred to the customer. For example, a units-of-delivery or a units-of-production method may sometimes understate an entity’s performance by excluding work in progress that is controlled by the customer. (See paragraph BC165 of ASU 2014-09.)

- An input method may better reflect progress toward complete satisfaction of a performance obligation over time when (1) the performance obligation consists of a series of distinct goods or services that meets the criteria in ASC 606-10-25-14(b) to be treated as a single performance obligation and (2) the effort required to create and deliver the first units is greater than the effort to create the subsequent units because of the effect of a “learning curve” of efficiencies realized over time. (See paragraph BC314 of ASU 2014-09.)

- An entity applying an input method must exclude from its measure of progress the costs incurred that (1) do not contribute to the entity’s progress in satisfying a performance obligation (e.g., the costs of unexpected amounts of wasted materials) and (2) are not proportionate to the entity’s progress in satisfying the performance obligation (e.g., the cost of obtaining goods from a vendor that accounts for most of the product’s cost). (See ASC 606-10-55-21.)
Connecting the Dots
In the life sciences industry, CROs often incur out-of-pocket expenses and “pass-through costs” related to payments made to investigators (physicians) who participate in the clinical studies being conducted. Under the new revenue standard, if the CRO activity is part of a combined performance obligation, these costs should generally be included in a CRO's measure of progress when a cost-based input measure is used to recognize revenue over time.

Multiple Measures of Progress Toward Complete Satisfaction of a Performance Obligation
CROs often provide multiple services for their customers (pharmaceutical and biotechnology entities). For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results.

Assume that a CRO concludes that its contract with a biotechnology customer contains a single performance obligation (i.e., in the context of the contract, the various services to be performed are not separable) and that the CRO concludes that the performance obligation is satisfied over time. Consequently, the CRO is required to identify an appropriate measure to depict progress toward complete satisfaction of its performance obligation (see ASC 606-10-25-31 through 25-37).

Question
When a single performance obligation satisfied over time consists of multiple promised goods or services, or both, can multiple measures of progress be used to depict an entity's progress toward complete satisfaction of that performance obligation?

Answer
No. ASC 606-10-25-32 states that an entity should apply a single measure of progress for each performance obligation. This applies even when that single performance obligation is made up of a number of goods or services.

Selecting a measure of progress may be challenging when a single performance obligation contains multiple goods or services or has multiple payment streams. Regardless of the number of goods, services, or payment streams in a performance obligation, an entity is required to identify a single measure of progress that appropriately reflects its progress toward complete satisfaction of the performance obligation.

Connecting the Dots
Under legacy guidance, some CROs apply input methods while others apply output methods, with outputs based on different measures of progress. The new revenue standard requires an entity to identify a single measure of progress that appropriately reflects its progress toward complete satisfaction of the performance obligation. As a result, CROs have generally concluded that input measures will be used under ASC 606.
Consignment Arrangements

Although physical possession is an indicator that control has transferred to the customer, ASC 606-10-25-30(c) cautions that there are some arrangements in which physical possession may not be indicative of control. One example is a consignment arrangement.

Consignment arrangements occasionally exist in the life sciences industry (e.g., a medical device may be delivered to a hospital under a consignment arrangement until the device is needed for a surgery). Under ASC 606, the accounting for consignment arrangements may be consistent with legacy guidance if control of the products delivered to a consignee does not transfer until the consignee sells the products to a third party.

Government Vaccine Stockpile Programs

In August 2017, the SEC issued an interpretive release to update previously issued guidance on accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into stockpiles related to the Vaccines for Children Program or the Strategic National Stockpile.

The update was provided to bring existing guidance into conformity with ASC 606. Under the guidance, vaccine manufacturers should recognize revenue when vaccines are placed into U.S. government stockpile programs because control of the vaccines has been transferred to the customer. However, these entities also need to evaluate whether storage, maintenance, and shipping and handling activities of vaccine stockpiles are separate performance obligations.

Licensing

Under the new revenue standard, the framework used to account for licensing of IP is essentially the same as the framework used to account for a sale of goods or services. That is, the five-step model is generally applied to licensing transactions as well. However, licensing of IP can take many forms, and the economics and substance of such transactions can often be difficult to identify. Determining how to account for licensing transactions will often depend on the specific facts and circumstances and will require the exercise of professional judgment. To help preparers exercise such judgment, the new revenue standard provides supplemental guidance on recognizing revenue from contracts related to the licensing of IP to customers. The scope of the guidance includes all licenses that provide a customer with rights to IP, except for certain software hosting arrangements.

In the evaluation of how to account for a licensing transaction under the new revenue standard, it is important for an entity to consider each of the five steps in the model (although, as discussed below, certain exceptions are provided for licensing transactions). Specifically, an entity will need to do each of the following:

- **Step 1: Identify the contract with the customer** — This step includes evaluating the enforceable rights and obligations (including implicit rights) of each party to the contract and determining whether amounts under the contract are collectible.

- **Step 2: Identify the performance obligation under the contract** — This includes determining whether the entity's obligation to transfer a license to a customer results in (1) a single promise that will be satisfied (i.e., a single performance obligation) or (2) multiple performance obligations. This step could also involve determining whether the license of IP is the predominant element in the arrangement.

- **Step 3: Determine the transaction price** — This includes identifying and, potentially, measuring and constraining variable consideration.
• **Step 4: Allocate the transaction price** — This includes considering whether the residual method could be used for determining the stand-alone selling price of one (or a bundle) of the performance obligations.

• **Step 5: Determining when control of the license is transferred to the customer** — This includes determining whether the license is transferred at a point in time (for a right to use IP) or over time (for a right to access IP).

Some of the key judgments an entity will need to make are likely to be in connection with step 2 (identify the performance obligations) and step 5 (recognize revenue) of the model. As part of step 2, an entity will need to evaluate license restrictions (and changes in any such restrictions) when determining whether the restrictions merely define the licenses (which may be the case when the restrictions are related to time or geography) or, in effect, give rise to multiple performance obligations (which may be the case when the restrictions change over the license period and require the entity to transfer additional rights to the customer).

As part of step 5, when an entity is determining whether it has granted a customer a right to use or a right to access its IP, it will need to (1) assess the nature of the promised license to determine whether the license has significant stand-alone functionality and (2) evaluate whether such functionality can be retained without ongoing activities of the entity. For licenses with significant stand-alone functionality, ongoing activities of the entity providing the license do not significantly affect the license’s functionality (i.e., its utility). However, certain licenses do not have significant stand-alone functionality and require ongoing activities from the entity to support or maintain the license’s utility to the customer. The nature of an entity’s license of IP will determine the pattern of transfer of control to the customer, which is either at a point in time (if the customer is granted a right to use the IP) or over time (if the customer is granted a right to access the IP).

For licensing transactions in which consideration is tied to the subsequent sale or usage of IP, the new revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, ASC 606-10-55-65 requires an entity to recognize revenue associated with a sales- or usage-based royalty promised in exchange for a license of IP when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs.

b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

**Connecting the Dots**

In the application of the sale- or usage-based royalty exception in ASC 606-10-55-65, it would not be appropriate for an entity to omit sales- or usage-based royalties from its financial statements merely because the associated sales data were received after the end of the reporting period or were not received when the financial statements were issued or available to be issued.

Some of the more common questions that life sciences entities have faced when considering the licensing guidance of the new revenue standard are discussed below.
Determining Whether the Sales- or Usage-Based Royalty Exception Applies to an In-Substance Sale of IP

**Question**

An entity may license IP to a customer under an arrangement that gives the customer exclusive use of the IP for a period that is substantially the same as the IP’s useful life. Is this type of arrangement within the scope of (1) the licensing implementation guidance in ASC 606-10-55-54 through 55-65B or (2) the general recognition and measurement model in the new revenue standard, which could result in a different pattern of revenue recognition? Specifically, does the sales- or usage-based royalty exception apply to an in-substance sale of IP?

**Answer**

The FASB considered, but rejected, expanding the scope of the royalty recognition constraint because of complexities in legal differences between a sale of IP and a license of IP. We generally believe that the legal form of the transaction will determine which revenue accounting guidance (i.e., the guidance on estimating royalties or the guidance on applying the royalty recognition constraint) is applicable.

Distinguishing Between an Attribute of a License and an Additional Promise

A contract with a customer may contain provisions that limit the customer's use of a license of IP to a specific period, a specific geographical region, or a specific use. For example, an entity may license drug distribution rights to a customer that can be (1) used for three years, (2) made available only to consumers in North America, and (3) used only for a specific drug indication. Often, such restrictions will be attributes of the license. That is, the restrictions will define the rights the customer has under the license. However, some restrictions, or changes in restrictions over time, will require an entity to transfer additional rights to a customer. Specifically, the amendments in ASU 2016-10 clarify that (1) certain contractual provisions indicate that an entity has promised to transfer additional rights (i.e., an additional license) to a customer and (2) promises to transfer additional rights should be accounted for as separate performance obligations.

**Question**

How should a life sciences entity determine whether contractual provisions represent an attribute of a license or an additional promise?

**Answer**

The determination of whether contractual provisions related to a license of IP represent an additional promise may require significant judgment. Contractual provisions (restrictions) that define the scope of a license of IP that has already been transferred to a customer would generally not be accounted for as a separate performance obligation. For example, a restriction that limits the use of a license to a five-year period would be an attribute of the single license. However, contractual provisions that define additional rights that will be transferred at a future date would generally be accounted for as a separate performance obligation, as illustrated in the example below.
Example

An entity transfers to a customer a two-year license of IP that can be used only in Jurisdiction A during year 1 but can be used in both Jurisdiction A and Jurisdiction B during year 2. In this example, the customer does not obtain control of the license in Jurisdiction B until year 2. That is, in year 2, the entity must transfer additional rights that entitle the customer to use the license in Jurisdiction B. Although the entity transfers the license to use the IP in Jurisdiction A at the beginning of year 1, the entity must still fulfill a second promise to deliver the license to use the IP in Jurisdiction B in year 2. Although the license of IP obtained by the customer in year 1 may be the same license of IP that will be used in year 2 (i.e., the customer currently controls the right to use or access the IP), the customer is precluded from using and benefiting from that license in Jurisdiction B until year 2. The obligation to transfer additional rights to the customer at the beginning of year 2 should be identified as an additional performance obligation under the contract with the customer.

Functional Versus Symbolic IP

In determining whether to recognize revenue from a license of IP over time or at a point in time, an entity needs to determine the nature of the licensing arrangement. The nature of the arrangement is determined on the basis of the entity’s promise to the customer and whether that promise (1) provides access to the IP throughout the license term (i.e., “right to access”) or (2) provides a right to use the IP as it exists at the point in time when control of the license is transferred to the customer (i.e., “right to use”). Revenue from a license that grants a right to access an entity’s IP is recognized over time since the customer simultaneously receives and consumes the benefits of the entity’s IP throughout the license periods (i.e., meets the requirement in ASC 606-10-25-27(a)). Revenue from a license that grants a right to use an entity’s IP is recognized at the point in time when control of the license is transferred to the customer.

To assist in the evaluation of whether the license provides the customer with a right to access or right to use the entity’s IP, the new revenue standard distinguishes between two types of IP: (1) functional and (2) symbolic.

Question

In the life sciences industry, are most licenses of IP of a functional or symbolic nature? What impact does the nature of a license have on the timing of revenue recognition?

Answer

Examples of licenses of functional IP could include software, drug compounds and formulas, and completed media content. In accordance with ASC 606-10-55-62, the nature of a license to functional IP that is distinct will provide a customer with the right to use an entity’s IP (i.e., point-in-time revenue recognition) unless (1) the entity’s ongoing activities that will not transfer promised goods to the customer (i.e., those not deemed to be additional promised goods to the customer) will significantly change the utility of the license and (2) the customer is contractually or practically required to use the updated IP once available. If these criteria are met, the nature of the license is a right to access the entity’s IP (i.e., a license for which revenue is recognized over time). As discussed in paragraph BC58 of ASU 2016-10, the FASB expected that at the time of issuance of ASU 2016-10, the criteria in ASC 606-10-55-62 “will be met only infrequently, if at all.” Consequently, revenue from a license of drug compounds and formulas that represents a
distinct performance obligation would generally represent a right to use an entity’s IP and would be recognized at the point in time when control of the license is transferred to the customer. However, ASC 606-10-55-58C states the following:

Notwithstanding paragraphs 606-10-55-58A through 55-58B, revenue cannot be recognized from a license of intellectual property before both:

a. An entity provides (or otherwise makes available) a copy of the intellectual property to the customer.

b. The beginning of the period during which the customer is able to use and benefit from its right to access or its right to use the intellectual property. That is, an entity would not recognize revenue before the beginning of the license period even if the entity provides (or otherwise makes available) a copy of the intellectual property before the start of the license period or the customer has a copy of the intellectual property from another transaction. For example, an entity would recognize revenue from a license renewal no earlier than the beginning of the renewal period.

Connecting the Dots

Because revenue from customer renewals of licenses of IP cannot be recognized before both of the conditions in ASC 606-10-55-58C are met, revenue from a renewal of a right-to-use license is not recognized until the beginning of the renewal period, rather than when the parties agree to the renewal. This requirement may result in a change in practice for life sciences entities that historically have recognized fees on renewal rather than at the beginning of the renewal term.

Considerations for Determining Whether a License Is Predominant

Under the sales- or usage-based royalty exception to the new revenue standard’s general rule requiring an entity to include variable consideration in the transaction price, if an entity is entitled to consideration in the form of a sales- or usage-based royalty, revenue is not recognized until (1) the underlying sales or usage has occurred and (2) the related performance obligation has been satisfied (or partially satisfied). That is, an entity is not required to estimate the amount of a sales- or usage-based royalty at contract inception; rather, revenue would be recognized when (or as) the subsequent sales or usage occurs (assuming that the associated performance obligation has been satisfied or partially satisfied).

As explained in ASC 606-10-55-65A, the sales- or usage-based royalty exception applies “when the royalty relates only to a license of intellectual property or when a license of intellectual property is the predominant item to which the royalty relates (for example, the license of intellectual property may be the predominant item to which the royalty relates when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates)” (emphasis added).

In the life sciences industry, licenses are often included with R&D services, manufacturing services, or both, with consideration in the form of a sales-based royalty. When the license and the services do not qualify as separate performance obligations, an entity will need to use significant judgment to assess whether the IP license is “the predominant item to which the royalty relates.”

Question

What factors should a life sciences entity consider in determining whether a license is predominant and therefore subject to the sales- or usage-based royalty exception?
**Answer**

The new revenue standard does not define “predominant.” However, ASC 606-10-55-65A notes that the license may be predominant “when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates.” Consequently, life sciences entities should consider the customer’s perspective of value and the relative importance and value of the promised goods or services. For example, in a combined license and R&D arrangement, an entity might consider the remaining clinical trial studies that need to be completed and the expected size of the market upon approval. Since different interpretations may arise in practice and the consequences of these differences could be significant to the timing of revenue recognition, entities are encouraged to contemporaneously document the basis for their conclusion on whether the license, rather than the other services, is predominant.

**Applicability of the Sales- or Usage-Based Royalty Exception to Sales-Based Milestones, Development-Based Milestones, or Guaranteed Minimum Royalties**

**Question**

Is the sales- or usage-based royalty exception applicable to sales-based milestones, development-based milestones, or guaranteed minimum royalties?

**Answer**

The sales- or usage-based royalty exception would apply to sales-based milestones as the payment becomes due on the basis of the subsequent sales to the customer. However, the exception cannot be applied to development-based milestone payments because these payments are not contingent on the sales to or usage by the customer. In addition, the exception cannot be applied to guaranteed minimum royalties because those payments are essentially fixed consideration. However, the exception would apply to any variable consideration that exceeds the fixed (guaranteed minimum) portion.

**Application of the Sales- or Usage-Based Royalty Exception to a Variable Royalty Arrangement With Declining Royalties**

An entity may enter into a contract with a customer in which the parties agree to a variable royalty arrangement with declining royalties. Consider the example below.

**Example**

An entity enters into a contract to provide a customer with a noncancelable license to the entity’s IP. The entity determines that the license is a right-to-use license (i.e., a license for which revenue is recognized at a point in time) for a three-year period. The customer’s estimated sales are expected to be approximately equal for each of the three years under license. For the use of the IP, the agreement requires the customer to pay the entity a royalty of 10 percent of the customer’s sales in year 1, 8 percent of the customer’s sales in year 2, and 6 percent of the customer’s sales in year 3.

**Question**

In the example above, should the entity account for the royalty payments by using the general model, which requires estimates of variable consideration?
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**Answer**

No. The entity should account for the royalty payments in a manner consistent with the legal form of the arrangement and in accordance with the exception to the variable consideration guidance for licenses of IP that include a sales- or usage-based royalty. Consequently, the entity would include the royalties in the transaction price on the basis of the applicable contractual rate and the customer’s sales in each year and then, in accordance with ASC 606-10-55-65, recognize revenue at the later of when (1) the “subsequent sale or usage occurs” or (2) the “performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).”

**Transition Methods**

Entities that have not yet adopted the new revenue standard should keep in mind that they have the option of using either a full retrospective or modified retrospective method to adopt the guidance in the new revenue standard:

- **Full retrospective application** — Retrospective application would take into account the requirements of ASC 250 (with certain practical expedients).

- **Modified retrospective application** — ASC 606-10-65-1(h) states that under the modified retrospective method, an entity recognizes “the cumulative effect of initially applying [ASU 2014-09] as an adjustment to the opening balance of retained earnings . . . of the annual reporting period that includes the date of initial application” (revenue in periods presented in the financial statements before that date is reported under guidance in effect before the change). When using this method, an entity applies the guidance in the ASU (as amended by ASU 2016-12) to either of the following:
  - Incomplete contracts (i.e., those contracts for which all (or substantially all) of the revenue has not been recognized in accordance with prior revenue guidance) as of the date of initial application.
  - All contracts as of, and new contracts after, the date of initial application.

Entities should carefully evaluate the respective advantages and disadvantages of each of the transition methods before selecting their method of adopting the new revenue standard. The transparent trend information provided under the full retrospective method may be most effective for entities that expect to experience a significant change. Also, entities that have significant deferred revenue balances may prefer a full retrospective method to ensure that such revenue is not “lost” from operations by its recognition as a cumulative-effect adjustment to retained earnings. However, the full retrospective method could require significant effort since the adjustments to prior reported results will change not only the revenue recognized but also the other “direct effects of a change” as defined in ASC 250.

**Special Considerations for Determining Which Transition Approach to Use**

**Question**

In the evaluation of the transition approach to use, are there any considerations that may be unique to life sciences entities?
Answer

As previously noted, collaborative arrangements are common in the life sciences industry, and many entities apply revenue literature directly or by analogy in the accounting for these arrangements. As life sciences entities with such collaborative arrangements evaluate which transition approach to use, they may need to consider the transition approach elected by their collaborative partners to ensure that the necessary information will be available to restate prior periods (if the full retrospective approach is used) or determine the cumulative-effect adjustment (if the modified retrospective approach is used).

In addition, life sciences entities should work with their collaboration partners to ensure that the parties are appropriately compensated for any changes in historical profit arising from differences in the amounts of revenue and costs from those previously reported. For any such changes in contractual cash flows that arise from these differences, entities are reminded that ASC 250-10-45-8 requires such “indirect effects” of changes in accounting principle to be reported in the period in which the accounting change is made (i.e., indirect effects are not included in the retrospective application).

Disclosure

As discussed in paragraph BC327 of ASU 2014-09, some of the main criticisms of the prior revenue guidance from regulators and users of the financial statements were related to disclosure requirements. Many entities’ disclosures contained boilerplate language that, broadly speaking, regulators and users found to be inadequate and lacking in cohesion with other disclosures; this made it hard for users to understand entities’ revenues, judgments related to revenue, and how revenue is related to an entity’s overall financial position. In addition, while disclosure has been a focus of the FASB and SEC in recent years, that focus has been primarily related to disclosure overload and extensive disclosures required on topics such as pensions, stock compensation, fair value, and income taxes. In response to stakeholder feedback, the FASB has aimed to make disclosures more effective, better coordinated, and less redundant. This sharper focus will most likely result in reduced disclosures in many cases. Although this has been an overall focus of the FASB and SEC, the lack of disclosure on revenue was highlighted as a key area for improvement during the development of the new revenue standard.

As a result, one of the goals of the FASB and IASB in the revenue project was to provide financial statement users with more useful information through improved disclosures. ASC 606-10-50-1 outlines the objective of the new revenue standard’s disclosure requirements as follows:

<table>
<thead>
<tr>
<th>ASC 606-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-1 The objective of the disclosure requirements in this Topic is for an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. To achieve that objective, an entity shall disclose qualitative and quantitative information about all of the following:</td>
</tr>
<tr>
<td>a. Its contracts with customers (see paragraphs 606-10-50-4 through 50-16)</td>
</tr>
<tr>
<td>b. The significant judgments, and changes in the judgments, made in applying the guidance in this Topic to those contracts (see paragraphs 606-10-50-17 through 50-21)</td>
</tr>
<tr>
<td>c. Any assets recognized from the costs to obtain or fulfill a contract with a customer in accordance with paragraph 340-40-25-1 or 340-40-25-5 (see paragraphs 340-40-50-1 through 50-6).</td>
</tr>
</tbody>
</table>
Some of the more common issues that life sciences entities have addressed when considering the disclosure requirements of the new revenue standard are discussed below.

**Level of Aggregation or Disaggregation**

To comply with the “entity-wide” disclosure requirements of ASC 280, many life sciences companies already disclose revenues from products for major medical treatments, revenues from different types of services (e.g., clinical development services vs. commercial services), revenues attributed to the entity's home country and other foreign countries, and the individual customers (e.g., wholesalers) whose purchases constitute 10 percent or more of the entity's revenues. These disclosures may not change for many life sciences companies, but entities are encouraged to document their consideration of the disaggregation categories outlined in ASC 606.

**Satisfied Performance Obligations**

ASC 606 requires disclosure of the amount of revenue recognized in the current period that is related to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods (e.g., because of changes in the variable consideration constraint). For example, development or approval-based milestone payments related to the delivery of a functional license of IP may have been fully constrained because of the uncertainty of achieving the milestones. Once the milestone payments are no longer constrained, an entity would be required to disclose the milestone payments recognized in the current period that are related to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods.

**Gross-to-Net Disclosures**

Many pharmaceutical companies currently disclose a rollforward of gross-to-net balance sheet reserves in MD&A. Some registrants also disclose a reconciliation of gross and net sales as reported in the statement of profit and loss. Some life sciences companies are considering the possibility of including these types of disclosures in the footnotes to the financial statements to meet the new revenue standard's disclosure requirements related to variable consideration, such as those related to disclosure of changes in estimates associated with the transaction price and estimates associated with the variable consideration.

For additional information about disclosures, see Deloitte's Revenue Roadmap.

**Legacy Guidance (ASC 605 and SAB Topic 13)**

As discussed above, the new revenue standard is effective for public entities for annual reporting periods beginning after December 15, 2017, and is effective for all other entities for annual reporting periods beginning after December 15, 2018. While many life sciences companies are focused on the implementation of the new revenue standard, the standard's effective date for private companies is generally January 1, 2019 (for entities with a December 31 year-end that have not elected to early adopt). Accordingly, revenue transactions of private companies that occur before the new revenue standard becomes effective for those companies must still be carefully analyzed under legacy guidance.
Topics of particular relevance to life sciences entities that continue to apply legacy revenue guidance include (1) the SAB Topic 13 requirements (e.g., sales price is fixed or determinable, collectibility is reasonably assured); (2) the accounting for multiple elements; (3) the ability to estimate returns; and (4) the accounting for discounts, rebates, and incentives. Further, biotechnology 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 under legacy guidance. Meanwhile, medical device companies that have not yet adopted the new revenue standard 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 for which the new revenue standard is not yet effective also rely heavily on collaborative arrangements to leverage expertise and manage risk. In accounting for collaborative arrangements under ASC 808, such entities often also apply legacy 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 biotechnology company performs contractual R&D services for a pharmaceutical company under the arrangement).

The sections below discuss (1) legacy guidance on some of the revenue recognition topics frequently encountered by life sciences entities and (2) SEC comment letter themes related to these topics.

**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.

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 GPO) 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:

<table>
<thead>
<tr>
<th>ASC 605-15</th>
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<tbody>
<tr>
<td><strong>25-1</strong> 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:</td>
</tr>
<tr>
<td>a. The seller’s price to the buyer is substantially fixed or determinable at the date of sale.</td>
</tr>
<tr>
<td>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. . . .</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>d. The buyer acquiring the product for resale has economic substance apart from that provided by the seller. . . .</td>
</tr>
<tr>
<td>e. The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer.</td>
</tr>
<tr>
<td>f. The amount of future returns can be reasonably estimated . . . .</td>
</tr>
</tbody>
</table>

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.

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).
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 returns for expired products (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 needed 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(a) 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.

**Connecting the Dots**

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.

Whether Revenue in a Pay-for-Performance Arrangement Should Be Recorded Upon Initial Sale or Deferred

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.

SEC Comment Letter Themes Related to Gross-to-Net Accounting

Examples of SEC Comments

- We note that you sell to distributors. Please disclose whether you offer your distributors rights of return, price protection, or other similar rights. If so, please disclose the accounting for these rights.
- You disclose that you provide discounts, special pricing, sales rebates, and price-breaks and you record the costs of all such programs as an adjustment to revenue. Please tell us, and disclose in future filings, when you record these amounts. Refer to ASC 605-50-25-3 and 605-50-45-2. Please explain and quantify for us the extent to which you recognize the consideration given to your customers at the date at which the sales incentive is offered instead of the date on which you recognize revenue.
- Tell us the amounts recognized in your statements of operations for the incentive programs and their related classification for each period presented. Please refer to ASC 605-50-50-1 and confirm that you will disclose this information in future filings.
- Please tell us the extent to which you make estimates of the amount of your sales incentives. Refer to ASC 605-50-25-4, 25-7, 25-8, and 25-9.
- We note that you sell your products to distributors . . . . Please revise your disclosure to summarize the significant terms of these arrangements with distributors, including any post shipment obligations and acceptance provisions that may exist and how you account for such obligations. Within your discussion, please explain if you grant price concessions to your distributors and, if so, how you account for price concessions. Refer to SAB Topic 13.B.
- We . . . note that you recognized revenue net of allowances, discounts, and other adjustments. Please tell us and revise your filing to explain the nature of the allowances, discounts, and other adjustments for which you adjust revenue. Explain how you account for these allowances, discounts, and other adjustments.
The recognition of revenue in the life sciences industry relies heavily on estimates and assumptions about returns and other potential adjustments to revenue. The importance of these estimates and assumptions underscores the need for entities to (1) focus on the criteria for recognizing revenue on the sale of goods or services and (2) consider various factors in estimating returns, chargebacks, rebates, discounts, promotions, shelf stock adjustments, and other adjustments to revenue. The SEC staff has commented on registrants’ accounting for their revenue arrangements and has required registrants to provide enhanced disclosure in future filings.

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 biotechnology 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

An optional purchase is a term in an arrangement that gives a customer the option to purchase products or services in the future.

**Question**

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.

Licensing and Supply Arrangement

Example

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:

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).


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]

SEC Comment Letter Themes Related to Multiple-Element Arrangements

Examples of SEC Comments

- Please tell us the significant deliverables within your multiple-element arrangements and any performance-, cancellation-, termination-, and refund-type provisions. Discuss how you considered ASC 605-25-25-5 and revise future filings to provide all of the disclosures required by ASC 605-25-50-2.
- Please tell us the significant factors, inputs, assumptions, and methods used to determine selling price (whether vendor-specific objective evidence, third-party evidence, or estimated selling price) for each of the significant deliverables. Refer to ASC 605-25-30-2 and 605-25-50-2.

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.

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)."
**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.

**Considerations for Determining When Milestone Payments Should Be Recognized in Revenue**

**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:

**Milestone**

An event having all of the following characteristics:

a. 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.

b. The event can only be achieved based in whole or in part on either of the following:
   1. The vendor’s performance
   2. A specific outcome resulting from the vendor’s performance.

c. If achieved, the event would result in additional payments being due to the vendor.

A milestone does not include events for which the occurrence is either of the following:

a. Contingent solely upon the passage of time

b. The 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 states, in part:

The consideration earned from the achievement of a milestone shall meet all of the following for the milestone to be considered substantive:

a. It is commensurate with either of the following:
   1. The vendor’s performance to achieve the milestone
   2. 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.

b. It relates solely to past performance.

c. 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.

**Medical Device Excise Tax**

As a result of the Patient Protection and Affordable Care Act of 2010, Section 4191 of the Internal Revenue Code (IRC) 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, included a two-year suspension of the tax, which applied to sales on or after January 1, 2016, and before January 1, 2018. On January 22, 2018, another two-year suspension was approved to retroactively delay the tax beginning December 31, 2017. The tax will now go into effect on January 1, 2020.

**Whether the MDET Is Within the Scope of ASC 605-45**

**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.
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 IP 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.

Considerations Relevant to the Accounting for a Collaborative Arrangement

**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 of the following:

- “[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, in accordance with 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 biotechnology company and pharmaceutical company agree to coproduce and commercialize a newly approved drug, the biotechnology company may also agree to provide the pharmaceutical company with R&D services that represent the biotechnology company’s ongoing major or central operations. In such cases, it may be appropriate for the biotechnology 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 about ultimate commercialization 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.

In addition, participants will 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 on the basis of 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.
Revenue Recognition

We believe that when an entity analogizes to authoritative accounting literature, all (as opposed to limited) aspects of that literature should be applied to the extent applicable. For example, a biotechnology 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 IP related to a drug candidate and (2) perform R&D services jointly with the pharmaceutical company. The biotechnology company may conclude that the revenue literature is applicable by analogy for determining the unit(s) of accounting, recognition, and measurement. Accordingly, if the biotechnology 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

In the past, the SEC staff has asked registrants about the nature of, and accounting for, their collaborative arrangements and has probed to better understand the basis for such accounting under U.S. GAAP. Inquiries to registrants have focused on the registrant’s conclusion about (1) whether certain transactions with the collaboration partner represent true vendor-customer activities, (2) the registrant’s accounting policies regarding separation (i.e., unit of accounting) and allocation (i.e., when multiple units exist) for collaborative arrangements, and (3) supplemental explanation of the registrant’s determination and disclosure of (a) the separation, allocation, recognition, and classification principles that were used to account for payments between collaboration partners and (b) 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 disclosure about registrants’ collaborative arrangements, including the overall effect of collaborative arrangements on the financial statements.

We have observed that the frequency of staff comments on registrants’ collaborative arrangements has decreased from prior years. However, as part of their implementation of the new revenue standard, registrants need to evaluate whether transactions between partners in a collaborative arrangement are within the scope of the new revenue standard. While ASC 606 does not change the guidance in ASC 808 on the income statement presentation, classification, and disclosure applicable to collaborative arrangements, it is important for registrants to understand and consider that an existing contract could be within the scope of both ASC 606 and ASC 808. As indicated in paragraph BC55 of ASU 2014-09:

The Boards noted that a contract with a collaborator or partner (for example . . . a collaborative arrangement within the scope of Topic 808, Collaborative Arrangements) also could be in the scope of Topic 606 if that collaborator or partner meets the definition of a customer for some or all the terms of the arrangement.

This is important because companies may have to assess the scope of both ASC 606 and ASC 808 for these types of arrangements. In addition, the Basis for Conclusions of ASU 2014-09 does not preclude companies from analogizing to the guidance in ASC 606 when accounting for collaborative arrangement transactions within the scope of ASC 808. Consequently, registrants should be mindful that the SEC staff may continue to ask them about their accounting policies for collaborative arrangements when ASC 606 is adopted.
On the Horizon

Background
As noted in the Collaborative Arrangements section above, while ASC 808 defines collaborative arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of accounting or (2) when the recognition criteria are met.

Because of these omissions, stakeholders, including representatives from the life sciences industry, have informed the FASB that there are questions in practice about the accounting for transactions between participants in a collaborative arrangement. These stakeholders have observed that entities currently apply different approaches to account for collaborative arrangements, with some entities applying the revenue guidance to some or all elements of the arrangement and other entities establishing accounting policies for the recognition and measurement of transactions between participants, which may or may not be consistent with the revenue guidance.

As a result of the diversity in practice and the uncertainty about the accounting model that applies to these arrangements, the Board commenced a project in November 2016 that is aimed at making targeted improvements to clarify when transactions between partners in a collaborative arrangement are within the scope of the revenue guidance.

Next Steps
As of the date of this publication, the FASB has reached several tentative decisions related to its project on targeted improvements to ASC 808 and authorized its staff to draft a proposed ASU for vote by written ballot that will be issued for public comment for a 45-day comment period. For more information about the status of the project, see the Board’s Project Update Web page.
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*

AICPA Issues Paper, *Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories*

AICPA Technical Questions and Answers, Q&A paragraph 2260.03, “Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit”

**FASB Accounting Standards Updates (ASUs)**


ASU 2018-01, *Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842*

ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

ASU 2017-11, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815); (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

ASU 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*

ASU 2017-07, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*

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 2016-17, *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 2016-13, *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 2016-02, *Leases (Topic 842)*


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

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


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 2014-10, 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 2014-02, Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council

ASU 2011-06, Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers — a consensus of the FASB Emerging Issues Task Force

ASU 2010-27, Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers — a consensus of the FASB Emerging Issues Task Force

ASU 2010-20, Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses

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

**FASB Accounting Standards Codification (ASC) Topics**

ASC 205, Presentation of Financial Statements

ASC 210, Balance Sheet

ASC 220, Income Statement — Reporting Comprehensive Income

ASC 230, Statement of Cash Flows

ASC 235, Notes to Financial Statements

ASC 250, Accounting Changes and Error Corrections

ASC 260, Earnings per Share

ASC 280, Segment Reporting

ASC 320, Investments — Debt and Equity Securities

ASC 321, Investments — Equity Securities

ASC 323, Investments — Equity Method and Joint Ventures

ASC 325, Investments — Other

ASC 326, Financial Instruments — Credit Losses

ASC 330, Inventory

ASC 350, Intangibles — Goodwill and Other

ASC 360, Property, Plant, and Equipment

ASC 410, Asset Retirement and Environmental Obligations
ASC 420, Exit or Disposal Cost Obligations
ASC 450, Contingencies
ASC 470, Debt
ASC 480, Distinguishing Liabilities From Equity
ASC 505, Equity
ASC 605, Revenue Recognition
ASC 606, Revenue From Contracts With Customers
ASC 610, Other Income
ASC 715, Compensation — Retirement Benefits
ASC 718, Compensation — Stock Compensation
ASC 720, Other Expenses
ASC 730, Research and Development
ASC 740, Income Taxes
ASC 805, Business Combinations
ASC 808, Collaborative Arrangements
ASC 810, Consolidation
ASC 815, Derivatives and Hedging
ASC 820, Fair Value Measurement
ASC 825, Financial Instruments
ASC 830, Foreign Currency Matters
ASC 840, Leases
ASC 842, Leases
ASC 845, Nonmonetary Transactions
ASC 915, Development Stage Entities
ASC 958, Not-for-Profit Entities
ASC 985, Software
**Proposed FASB Accounting Standards Updates (Proposed ASUs)**

Proposed ASU 2018-200, *Leases (Topic 842): Targeted Improvements*


FASB Proposed Accounting Standards Update 2017-280, *Consolidation (Topic 812): Reorganization*


Proposed ASU 2017-220, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

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

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


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

**Other FASB Proposal**


**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 Interpretations (Pre-Codification Literature)**

FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*

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 (Pre-Codification Literature)**
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 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)”

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

Issue 00-21, “Revenue Arrangements With Multiple Deliverables”

**PCAOB Auditing Standard**

**SEC C&DI Topic**
Non-GAAP Financial Measures

**SEC Interpretive Release**
33-10403, *Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*

**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 103, “Business; Legal Proceedings.”

**SEC Regulation S-X**
Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired”

Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”

Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired”
Rule 4-08(g), “General Notes to Financial Statements; Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”

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

**SEC Staff Accounting Bulletins (SABs)**

SAB Topic 1.M, “Financial Statements; Materiality”

SAB Topic 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”

SAB Topic 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidies”

SAB Topic 13, “Revenue Recognition”

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

SAB Topic 13.B, “Revenue Recognition; Disclosures”

SAB 116, “Staff Accounting Bulletin No. 116”

SAB 118, codified as SEC Staff Accounting Bulletin Topic 5.EE, “Miscellaneous Accounting; Income Tax Accounting Implications of the Tax Cuts and Jobs Act”

**Internal Revenue Code (IRC)**

IRC Section 78, “Gross Up for Deemed Paid Foreign Tax Credit”

IRC Section 163(j), “Interest; Limitation on Business Interest”

IRC Section 199, “Income Attributable to Domestic Production Activities”

IRC Section 383, “Special Limitations on Certain Excess Credits, Etc.”

IRC Section 787, “Termination of Private Foundation Status”

IRC Section 965, “Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation”

IRC Section 4191, “Medical Devices”

**International Standards**

IFRS 16, *Leases*

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*
### Appendix B — Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFS</td>
<td>available for sale</td>
</tr>
<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
</tr>
<tr>
<td>AMT</td>
<td>alternative minimum tax</td>
</tr>
<tr>
<td>AOCl</td>
<td>accumulated other comprehensive income</td>
</tr>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
</tr>
<tr>
<td>APIC</td>
<td>additional paid-in capital</td>
</tr>
<tr>
<td>ASC</td>
<td>FASB Accounting Standards Codification</td>
</tr>
<tr>
<td>ASU</td>
<td>FASB Accounting Standards Update</td>
</tr>
<tr>
<td>BCF</td>
<td>beneficial conversion feature</td>
</tr>
<tr>
<td>BEAT</td>
<td>base erosion anti-abuse tax</td>
</tr>
<tr>
<td>BEMTA</td>
<td>base erosion minimum tax amount</td>
</tr>
<tr>
<td>BPD</td>
<td>branded prescription drug</td>
</tr>
<tr>
<td>BOLI</td>
<td>bank-owned life insurance</td>
</tr>
<tr>
<td>CAM</td>
<td>critical audit matter</td>
</tr>
<tr>
<td>C&amp;DI</td>
<td>SEC Compliance and Disclosure Interpretation</td>
</tr>
<tr>
<td>CECL</td>
<td>current expected credit loss</td>
</tr>
<tr>
<td>CFC</td>
<td>controlled foreign corporation</td>
</tr>
<tr>
<td>CODDM</td>
<td>chief operating decision maker</td>
</tr>
<tr>
<td>COLI</td>
<td>corporate-owned life insurance</td>
</tr>
<tr>
<td>CRO</td>
<td>contract research organization</td>
</tr>
<tr>
<td>CTA</td>
<td>cumulative translation adjustment</td>
</tr>
<tr>
<td>DCPs</td>
<td>disclosure controls and procedures</td>
</tr>
<tr>
<td>DTA</td>
<td>deferred tax asset</td>
</tr>
<tr>
<td>DTL</td>
<td>deferred tax liability</td>
</tr>
<tr>
<td>EBITDA</td>
<td>earnings before interest, taxes, depreciation, and amortization</td>
</tr>
<tr>
<td>EITF</td>
<td>FASB Emerging Issues Task Force</td>
</tr>
<tr>
<td>E&amp;P</td>
<td>earnings and profits</td>
</tr>
<tr>
<td>EPS</td>
<td>earnings per share</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FAQ</td>
<td>frequently asked question</td>
</tr>
<tr>
<td>FASB</td>
<td>Financial Accounting Standards Board</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FDII</td>
<td>foreign derived intangible income</td>
</tr>
<tr>
<td>FIFO</td>
<td>first in, first out</td>
</tr>
<tr>
<td>FIN</td>
<td>FASB Interpretation Number (superseded)</td>
</tr>
<tr>
<td>FOB</td>
<td>free on board</td>
</tr>
<tr>
<td>GAAP</td>
<td>generally accepted accounting principles</td>
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<tr>
<td>GILTl</td>
<td>global intangible low-taxed income</td>
</tr>
<tr>
<td>GPO</td>
<td>group purchasing organization</td>
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<tr>
<td>IAS</td>
<td>International Accounting Standard</td>
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<tr>
<td>IASB</td>
<td>International Accounting Standards Board</td>
</tr>
<tr>
<td>IFRS</td>
<td>International Financial Reporting Standard</td>
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<tr>
<td>IIR</td>
<td>investigator-initiated research</td>
</tr>
<tr>
<td>IP</td>
<td>intellectual property</td>
</tr>
<tr>
<td>IPO</td>
<td>initial public offering</td>
</tr>
<tr>
<td>IPR&amp;D</td>
<td>in-process research and development</td>
</tr>
<tr>
<td>IRC</td>
<td>Internal Revenue Code</td>
</tr>
<tr>
<td>IRS</td>
<td>Internal Revenue Service</td>
</tr>
<tr>
<td>IT</td>
<td>information technology</td>
</tr>
<tr>
<td>LIFO</td>
<td>last in, first out</td>
</tr>
<tr>
<td>LLC</td>
<td>limited liability company</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
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</tr>
<tr>
<td>LP</td>
<td>limited partnership</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>merger and acquisition</td>
</tr>
<tr>
<td>MD&amp;A</td>
<td>Management's Discussion and Analysis</td>
</tr>
<tr>
<td>MDET</td>
<td>medical device excise tax</td>
</tr>
<tr>
<td>MSL</td>
<td>medical science liaison</td>
</tr>
<tr>
<td>NFP</td>
<td>not-for-profit entity</td>
</tr>
<tr>
<td>NOL</td>
<td>net operating loss</td>
</tr>
<tr>
<td>OCI</td>
<td>other comprehensive income</td>
</tr>
<tr>
<td>OEM</td>
<td>original equipment manufacturer</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>PBE</td>
<td>public business entity</td>
</tr>
<tr>
<td>PCAOB</td>
<td>Public Company Accounting Oversight Board</td>
</tr>
<tr>
<td>PCC</td>
<td>Private Company Council</td>
</tr>
<tr>
<td>PCD asset</td>
<td>purchased financial asset with credit deterioration</td>
</tr>
<tr>
<td>PRV</td>
<td>priority review voucher</td>
</tr>
<tr>
<td>PTRS</td>
<td>probability of technical and regulatory success</td>
</tr>
<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>R&amp;E</td>
<td>research and experimentation</td>
</tr>
<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
</tr>
<tr>
<td>ROU</td>
<td>right-of-use</td>
</tr>
<tr>
<td>SAB</td>
<td>SEC Staff Accounting Bulletin</td>
</tr>
<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
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<tr>
<td>SFC</td>
<td>specified foreign corporation</td>
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<tr>
<td>SIFMA</td>
<td>Securities Industry and Financial Markets Association</td>
</tr>
<tr>
<td>T.D.</td>
<td>Treasury Decision</td>
</tr>
<tr>
<td>TRG</td>
<td>transition resource group</td>
</tr>
<tr>
<td>UTB</td>
<td>unrecognized tax benefit</td>
</tr>
<tr>
<td>VIE</td>
<td>variable interest entity</td>
</tr>
<tr>
<td>WAC</td>
<td>wholesaler acquisition cost</td>
</tr>
</tbody>
</table>
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