

Technical Line

FASB – final guidance

The new revenue recognition standard – life sciences

The new revenue standard could result in significant changes in practice for life sciences entities.

What you need to know

- ▶ The new revenue recognition standard is more principles-based than current revenue guidance and will require life sciences entities to exercise more judgment.
- ▶ Life sciences entities may have to change how they estimate variable consideration and, as a result, may recognize revenue earlier than they do today. Entities also may need to change the way they account for reseller arrangements and recognize revenue for licenses.
- ▶ The new standard is effective for public entities for fiscal years beginning after 15 December 2016, including interim periods within those years, and for nonpublic entities in fiscal years beginning after 15 December 2017 and interim periods within fiscal years beginning after 15 December 2018.

Overview

Life sciences entities may need to change certain revenue recognition practices as a result of the new revenue recognition standard jointly issued by the Financial Accounting Standards Board (the FASB) and the International Accounting Standards Board (the IASB) (collectively, the Boards). The new revenue recognition standard will supersede virtually all revenue recognition guidance in US GAAP and IFRS, including industry-specific guidance that life sciences entities use today.

The new standard provides accounting guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers (unless the contracts are in the scope of other US GAAP requirements, such



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as the leasing literature). The guidance also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets, such as intangible assets and property and equipment, including real estate.

Our Technical Line, [A closer look at the new revenue recognition standard](#) (SCORE No. BB2771), provides an in-depth discussion of the new revenue standard. This publication summarizes the key implications for life sciences entities.

Life sciences entities also may want to monitor the discussions of the Boards' Joint Transition Resource Group for Revenue Recognition (TRG). The Boards created the TRG to help them determine whether more implementation guidance or education is needed. The TRG won't make formal recommendations to the Boards or issue guidance. Separately, the American Institute of Certified Public Accountants (AICPA) has established 16 industry task forces to help develop a new Accounting Guide on Revenue Recognition and to aid industry stakeholders in implementing the standard. The AICPA has not established a task force for the life sciences industry. Any views discussed by the TRG or guidance produced by the AICPA is non-authoritative.

The views we express in this publication are preliminary. We may identify additional issues as we analyze the standard and entities begin to interpret it, and our views may evolve during that process. As our understanding of the standard evolves, we will update our guidance.

Key considerations

Life sciences entities may have to change their processes and controls for making estimates and possibly recognize revenue earlier than they do today to comply with the standard's requirement to estimate variable consideration.

In addition, complex arrangements with multiple promised goods and services (e.g., a license of a product candidate combined with research and development services, or a medical device combined with installation services and a maintenance agreement) will require careful consideration to determine whether they have separate performance obligations.

Collaboration agreements

Life sciences entities frequently enter into collaboration agreements with other parties in which the counterparty may be a collaborator that shares in the risks and benefits of developing a product to be marketed rather than a customer. An example would be two pharmaceutical companies that collaborate on the development of an experimental product candidate.

Life sciences entities may find it challenging to determine whether their collaboration agreements are in the scope of the new revenue standard. Identifying the customer can be difficult, especially when multiple parties are involved. This evaluation may require significant judgment, and the new guidance does not provide any additional considerations in this area. A life sciences entity's collaboration agreement may contain a vendor-customer aspect that would be at least partially within the scope of the new revenue guidance if that collaborator or partner meets the definition of a customer.

Today, these arrangements generally are in the scope of Accounting Standards Codification (ASC) 808, *Collaborative Arrangements*, which allows an entity to make a policy election to apply today's revenue recognition guidance by analogy for the income statement classification of collaboration arrangements. The implementation guidance in the consequential amendments states that entities will have to determine whether they can apply the new revenue guidance by analogy even though arrangements with counterparties that are not customers (i.e., some arrangements within the scope of ASC 808) are not in the scope of the new standard.

Estimating variable consideration

In life sciences arrangements, a portion of the transaction price can often vary in amount and timing due to rebates, incentives, rights of return, performance bonuses, milestones, other contingencies (e.g., future royalties) or concessions. The new standard requires an entity to estimate variable consideration and include in the transaction price amounts for which it is probable that a significant revenue reversal will not occur (i.e., they apply a constraint on variable consideration).

Under today's guidance, an entity cannot recognize consideration that is contingent on a future event (e.g., a performance bonus, a milestone payment) until that event occurs. Under the new standard, life sciences entities will have to estimate the consideration to which they expect to be entitled from these bonuses and milestone payments and, after considering the constraint, may recognize some portion of these payments before they achieve the performance metric or milestone. As a result, a life sciences entity may recognize revenue related to some of these items sooner than it does today.

The requirement to estimate variable consideration will likely require changes to a life sciences entity's accounting policies, accounting systems and/or internal control over financial reporting. For example, life sciences entities may need to adjust their processes and controls for calculating rebates on product sales due to the requirement in the new standard to estimate these rebates using a most likely amount or expected value approach.

Rights of return

A right of return creates variable consideration that an entity will estimate and include in the transaction price. In doing so, an entity will consider the products it expects to be returned and exclude the consideration associated with those products to determine the amount to which it expects to be entitled. While an entity may need to change the method it uses to make this estimate, it is unclear whether the estimate amount will change significantly.

An entity will recognize the amount of expected returns as a refund liability, representing its obligation to return the customer's consideration. The standard also requires a return asset to be recognized for the right to recover the product, but this requirement likely will not affect pharmaceutical companies because returns frequently have no value due to product expiration or requirements to destroy returned inventory. Entities must present the return asset (if recognized) separately from both the refund liability (i.e., on a gross basis) and inventory.

Reseller and distributor arrangements

Under the new standard, life sciences entities that sell their products through distributors or resellers (collectively, resellers) may recognize revenue sooner than they currently do. Today, some entities that use resellers wait until the product is sold to the end customer to recognize revenue (under the sell-through method) because they do not meet all of the criteria to recognize revenue when they deliver the product to the reseller. They may switch to recognizing revenue when they transfer the products to the reseller (under the sell-in method) once they gain enough experience to estimate returns and other variable components of pricing (e.g., chargebacks).

Under the new standard, the practice of using a sell-through method is no longer acceptable if the only uncertainty is the variability in the pricing. This is because the standard requires an entity to estimate the variable consideration (i.e., the end sales price) based on the information available, taking into consideration the effect of the constraint on variable consideration. That said, in some cases, the outcomes under the new and current methods may be similar.

Applying the new guidance to reseller arrangements will require significant judgment. Entities may also have to change their processes and information systems.

Life sciences entities may recognize some portion of bonus and milestone payments before achieving the performance metric or milestone.

Licenses of intellectual property

Life sciences entities' arrangements frequently include licenses of intellectual property (IP) with other goods and services, such as research and development or manufacturing services. Entities will have to consider whether such contracts include distinct licenses of IP in order to apply the guidance appropriately. This evaluation will require significant judgment. Example 56 in the standard (ASC 606-10-55-368 through 55-374) walks through the accounting for a life sciences arrangement for a license of IP and manufacturing services.

After determining that an IP license is distinct, an entity will have to analyze whether the license is a right to access the IP or a right to use the IP. Revenue allocated to a license that conveys a right to access will be recognized over the license period. Revenue allocated to a license that conveys a right to use will be recognized when the license is provided. The determination will be based on the facts and circumstances, and implementation questions already have arisen.

The guidance creates an exception to the variable consideration requirements for sales- and usage-based royalties from licenses of IP, which generally will be recognized when the sales or usage occurs. This will likely result in accounting that is consistent with current practice.

It is unclear whether this exception will apply to royalties that relate to both licensed IP and other goods or services in a contract (e.g., a contract with two performance obligations, a distinct product candidate license and research and development services that would be provided over time and would affect the amount of royalties earned). The TRG has discussed a number of views, including whether the exception should apply solely to a license that is a separate performance obligation or whether it should apply regardless of whether the royalty also relates to a non-license good or service. It is not yet clear whether the Boards will provide additional guidance. Life sciences entities should monitor developments.

Next steps

- ▶ Entities should perform a preliminary assessment on how they will be affected as soon as possible so they can determine how to prepare to implement the new standard. While the effect on entities will vary, some may face significant changes in revenue recognition. All entities will need to evaluate the requirements of the new standard and make sure they have processes and systems in place to collect the necessary information to implement the standard, even if their accounting results won't change significantly or at all.
- ▶ Entities also may want to monitor the discussions of the Boards, the Securities and Exchange Commission (SEC) staff and the TRG to discuss interpretations and application of the new standard to common transactions.
- ▶ Public entities also should consider their communication plans with investors and other stakeholders, including their plan for disclosures about the effects of new accounting standards discussed in SEC Staff Accounting Bulletin (SAB) Topic 11.M. The SEC staff has indicated it expects an entity's disclosures to evolve in each reporting period as more information about the effects of the new standard becomes available, and the entity should disclose its transition method once it selects it.

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