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Strategies for Life Sciences Companies to Stay Ahead of Changing Revenue Recognition Guidelines

What the New Guidelines Mean for Life Sciences Companies

In 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, which introduced new Accounting Standards Codification® (ASC) Topic 606, *Revenue from Contracts with Customers*.

The main principle of Topic 606 is that a seller should recognize revenue when the customer obtains control of a good or service, in an amount the seller expects to be entitled in exchange for those goods or services.

The new guidelines will supersede long-standing, industry-specific rules. Familiar concepts such as persuasive evidence of an agreement, delivery, and fixed or determinable fees will be eliminated in favor of new, more principles-based rules.

Companies will have to apply significant judgment to determine the timing and amount of revenue recognition, perhaps more so than under today's generally accepted accounting principles (GAAP). This may be challenging for companies that have grown accustomed to today's rigid, rules-based revenue recognition requirements.

For life sciences companies, the new revenue rules will have the greatest impact on collaboration and out-licensing arrangements. Even more straightforward transactions, such as the sale of medical products, might be accounted for very differently under the new guidelines.

Overview

Since the initial release in 2014, the FASB has issued multiple amendments to the revenue guidelines based on operational issues raised by the Transition Resource Group and other practitioners.

These amendments include Accounting Standards Updates:

- 2015-14 (deferring the effective date of the new revenue rules by one year)
- 2016-08 (gross versus net revenue presentation)
- 2016-10 (identifying performance obligations and accounting for intellectual property licenses)
- 2016-12 (narrow scope improvements and practical expedients)
- 2016-20, (technical corrections and improvements to Topic 606, *Revenue from Contracts with Customers*)

After years of deliberation, the FASB issued final revenue recognition guidelines.

These guidelines introduce a fundamentally different model for recognizing revenue versus legacy GAAP. The revenue recognition model in Topic 606 applies to nearly all types of revenue-generating transactions.

Once Topic 606 becomes effective, most of today's industry-specific revenue practices will be eliminated.

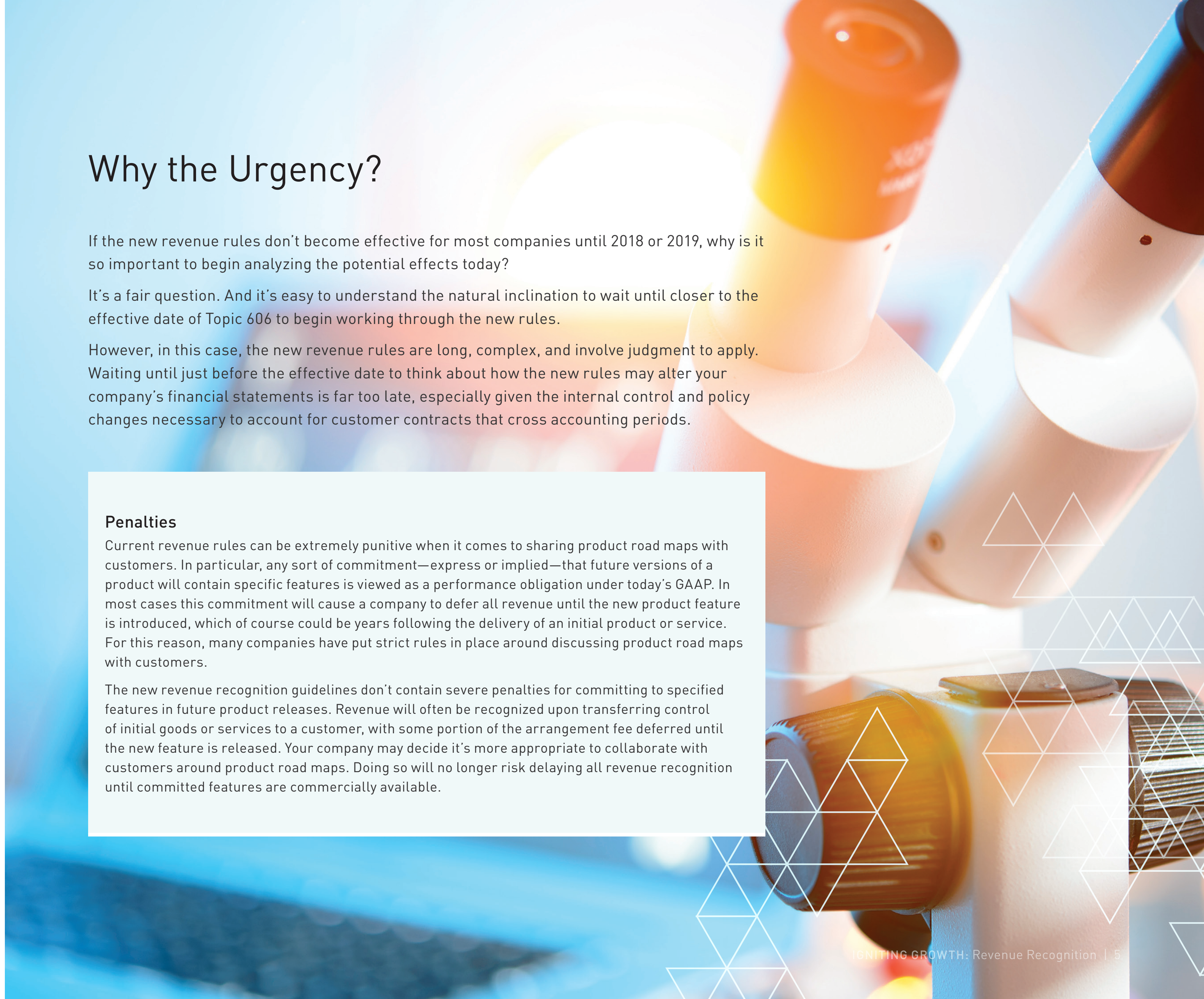
This includes the long-standing software revenue recognition guidelines in ASC Subtopic 985-605 as well as technical practice aids and other industry interpretations that have been developed and applied consistently over the past 20 years.

Effective Dates

For **public entities**, the new rules become effective for annual reporting periods beginning on or after December 15, 2017, and related interim periods.

For **nonpublic entities**, the rules are effective for annual reporting periods beginning on or after December 15, 2018, and interim periods beginning after December 15, 2019.

All companies are permitted to **early adopt** the new rules for annual periods beginning on or after December 15, 2016.



Why the Urgency?

If the new revenue rules don't become effective for most companies until 2018 or 2019, why is it so important to begin analyzing the potential effects today?

It's a fair question. And it's easy to understand the natural inclination to wait until closer to the effective date of Topic 606 to begin working through the new rules.

However, in this case, the new revenue rules are long, complex, and involve judgment to apply. Waiting until just before the effective date to think about how the new rules may alter your company's financial statements is far too late, especially given the internal control and policy changes necessary to account for customer contracts that cross accounting periods.

Penalties

Current revenue rules can be extremely punitive when it comes to sharing product road maps with customers. In particular, any sort of commitment—express or implied—that future versions of a product will contain specific features is viewed as a performance obligation under today's GAAP. In most cases this commitment will cause a company to defer all revenue until the new product feature is introduced, which of course could be years following the delivery of an initial product or service. For this reason, many companies have put strict rules in place around discussing product road maps with customers.

The new revenue recognition guidelines don't contain severe penalties for committing to specified features in future product releases. Revenue will often be recognized upon transferring control of initial goods or services to a customer, with some portion of the arrangement fee deferred until the new feature is released. Your company may decide it's more appropriate to collaborate with customers around product road maps. Doing so will no longer risk delaying all revenue recognition until committed features are commercially available.

THE FASB'S FIVE-STEP APPROACH

These required steps can help you determine when revenue from customer contracts should be recognized:

STEP 1
Identify the contract with a customer

A contract is in the scope of Topic 606 if:

- The parties have approved the contract and are committed to performing their obligations.
- Each party's rights regarding the goods and services to be transferred can be identified.
- The payment terms are identifiable—and it's probable the seller will collect.
- The arrangement has commercial substance.

STEP 2
Identify the separate performance obligations in the contract

A performance obligation represents a distinct product or service within a broader contract that the seller has promised to deliver to the customer. A seller should:

- Identify any performance obligations within a contract
- Allocate a portion of the total contract price to each distinct performance obligation
- Recognize as revenue the value assigned to a particular performance obligation, once the company satisfies it

Performance obligations can be both specified deliverables and implied or unspecified obligations based on the terms and conditions of the contract.

STEP 3
Determine the transaction price

When calculating the transaction price, Topic 606 requires companies to consider:

- Potential discounts
- Concessions
- Rights of return
- Liquidated damages
- Performance bonuses
- Other forms of variable consideration

When estimating the amount of variable consideration to include in the transaction price, companies should look at the stated terms of the customer contract as well as any past business practices that provided refunds or concessions or may provide rebates or other credits to specific customers based on the seller's intentions.

Here's an example of variable consideration for a life sciences company:

- Upon enrollment of the first patient in a Phase II clinical trial, an entity will receive a $50 million milestone payment.
- The owner of intellectual property (IP) will receive royalties of 5 percent on all sales of product containing that IP.

STEP 4
Allocate the transaction price to the separate performance obligations in the contract

A major change is the elimination of vendor-specific objective evidence (VSOE) as one of the requirements to recognize revenue in some arrangements involving software. To perform the allocation, the business should first try to determine the stand-alone selling price of each distinct performance obligation. If an entity doesn't sell a particular performance obligation on a stand-alone basis, it will have to estimate the stand-alone selling price. Techniques to make such estimates include:

- **Top-down approach.** A company can work with its sales team to develop a price it believes the market would be willing to pay for its goods or services.
- **Bottom-up approach.** A company can also estimate the stand-alone selling price for a good or service based on a cost-plus methodology—estimating its costs to provide a good or service and adding a reasonable margin for its production and selling efforts.

STEP 5
Recognize revenue when (or as) the entity satisfies a performance obligation

Under ASC Topic 606, a company will recognize revenue each time a company will recognize revenue as it satisfies a performance obligation. These principles may result in very different patterns of revenue recognition compared to legacy GAAP. As an example, the new revenue recognition guidance eliminates the sell-through method.

Other considerations in this step:

Refund Rights. When a good or service is sold together with a refund right, a company should record:

- Revenue for the transferred goods or services in the amount of consideration to which the company expects to be entitled. No revenue would be recognized for products expected to be returned or services expected to be refunded.
- A refund liability for any consideration received (or in some cases receivable) that's expected to be refunded.
- As applicable, an asset—and corresponding adjustment to cost of goods sold (COGS)—for a company's right to recover products from customers upon settling the refund liability.

Control Transfers Over Time. In some situations, control over a good or service isn't transferred at a point in time but rather over time. When revenue is recognized over time, Topic 606 allows companies to measure performance using either input measures, such as those based on costs or labor hours incurred, or output measures, such as milestones or units produced.

Licenses. Topic 606 specifies whether revenue from granting a license should be recognized at a point in time or over time. If a license represents a distinct performance obligation, revenue would be recognized one of two ways:

- If the underlying intellectual property (IP) to which the license relates is "functional," then revenue is recognized at a point in time—namely, when control of the license is transferred to the customer at the beginning of the license period.
- If the underlying IP is "symbolic," then revenue from the performance obligation will be recognized over time. The IP doesn't have significant standalone functional value; instead, it provides utility in the form of access to the entity's past or ongoing activities.

The new revenue rules are long, complex, and involve judgment to apply. Waiting until just before the effective date to think about how the new rules may alter your company's financial statements is far too late.

What Will Change?

For life sciences companies, the new revenue rules will impact collaboration and out-licensing arrangements. However, even simple transactions, such as the sale of medical devices or pharmaceutical products, may also be accounted for differently.

Beyond financial reporting, there may also be tax implications that should be considered when it comes to certain business practices. These may include:

- Acceleration of taxable income and tax payments due
- New book-tax differences and changes to deferred taxes
- Possible accounting method changes
- Sales and use tax

The new rules may require arrangement consideration to be allocated to performance obligations differently from legacy GAAP. In fact, the allocations may be inconsistent with the breakdown on the customer invoice.

Companies should identify which taxing authorities follow GAAP allocation rules—there may be quite a few—and update tax compliance systems because some obligations may be subject to sales and use tax while others may not.

Examples

Although these hypothetical scenarios don't present enough facts to fully conclude on the accounting treatment, it's important to note the types of analyses companies will perform under the new revenue guidelines and the important judgments that will be required.

SCENARIO 1: COLLABORATION AND OUT-LICENSING ARRANGEMENT

Let's assume a biotech company out-licenses a drug compound under development to a global pharmaceutical company. Biotech agrees to perform R&D activities with the goal of commercializing the compound. It receives an up-front payment of $10 million and is entitled to milestone payments of $50 million each upon enrollment of 100 patients in a Phase III clinical trial and regulatory approval. It will also receive royalties on any sales of commercialized product.

The following outlines some of the questions Biotech would have to address and the judgments it would have to make at each step of the revenue recognition process.

Step 1: Identify the Contract with a Customer

Is the global pharmaceutical company a customer? That is, will it be receiving goods and services in exchange for consideration? Or is it instead a partner in a collaboration agreement, in which both parties are actively participating in developing a product for sale?

If the pharmaceutical company's a partner in a collaboration agreement, the new revenue guidelines don't apply. Biotech would apply other GAAP, such as ASC Topic 808, to account for the arrangement. However, if the pharmaceutical company is indeed a customer, then Biotech would continue with the five-step revenue recognition process.

Step 2: Identify the Separate Performance Obligations in the Contract

Would the license to the drug compound and the research services represent separate performance obligations? Is the nature of the promise Biotech made to its customer to transfer two individual goods and services? Or has it instead committed to transfer a combined item (a fully developed and approved drug compound), for which the license and research services are inputs?

If the license and the research services are distinct performance obligations, the arrangement would contain two accounting units. Otherwise, it would contain just a single combined performance obligation, which would affect the timing of when revenue from the contract would be recognized. In practice, identifying the separate performance obligations within a customer contract will likely be one of the more challenging and judgmental aspects of applying the new revenue rules.

Step 3: Determine the Transaction Price

Should the potential milestone payments and sales royalties be considered part of the transaction price? Under today's GAAP, the milestone payments are often recognized as revenue in their entirety once the milestone is achieved.

However, the new revenue guidelines may require companies to recognize estimated milestone payments in advance of actually achieving the milestone. Yet for sales royalties on licensed intellectual property, Topic 606 prohibits revenue recognition until the underlying sale has actually occurred, similar to today's accounting requirements.

Step 4: Allocate the Transaction Price to the Separate Performance Obligations in the Contract

The new revenue guidelines require the use of a relative stand-alone selling price method to allocate the transaction price to separate performance obligations. But operationally, how would Biotech estimate the stand-alone selling prices of the license and the research services, especially when similar licenses or services haven't previously been sold on a separate basis?

Here's another complexity: Assume both potential milestone payments weren't initially included in the estimated transaction price, but now Biotech believes the first milestone will be achieved. Should that milestone payment be allocated to the delivered license, to the R&D services, or to a combination of both using a relative selling price approach?

Step 5: Recognize Revenue When (or as) the Entity Satisfies a Performance Obligation

Assuming the license represents a separate performance obligation, should Biotech recognize revenue upon its delivery to the global pharmaceutical company? Or over the period of time the customer will benefit from the license?

To answer this question, Biotech will have to evaluate whether the intellectual property underlying the license is functional or symbolic. That is, does the license allow the customer:

- To use Biotech's intellectual property as it exists at a point in time, meaning the underlying intellectual property has significant standalone functionality

-or-

- To access Biotech's evolving technology over a period of time, granting in essence a symbolic license that provides value via the customer's continued association with Biotech throughout the license period

SCENARIO 2:
SALE OF MEDICAL DEVICES

Let's say a medical devices company, which we'll refer to as MD, receives regulatory clearance to begin selling a new medical device. Following this approval, MD readies its plant to produce large quantities of the device. In addition, MD's sales lead contracts to sell the devices to one of the world's leading distributors and earns a sizable commission for her efforts. Specifically, the distributor places an order for 100,000 units of the new device. MD produces the units and, at the customer's direction, ships 60,000 completed units while storing the rest in its warehouse. The parties agree to this arrangement since it's cheaper to manufacturer in bulk and because the products have a long shelf life.

Let's look at a few of the issues MD would need to consider in accounting for the contract with its customer.

First, by storing 40,000 of the ordered units, MD has entered into a bill-and-hold arrangement. In almost every situation, current GAAP would preclude revenue recognition until the units are delivered to the final customer location. Under the new rules, MD may have two performance obligations—producing units and storing them. Revenue from the former would be recognized when control transfers to the distributor. Revenue from the latter would be recognized over time. More facts would be required to formally conclude. In fairness, the accounting for bill and hold sales under Topic 606 is expected to be the same as today's GAAP requirements in most situations.

Second, assume MD plans to protect its customer from any risk of damage while the 60,000 units are in transit, even though legally that risk has been transferred to the customer at shipping point per the terms of the contract. Under current GAAP, companies may not recognize revenue until the products arrive at the final customer location because substantially all of the risks and rewards of ownership don't pass to the customer until that time.

But under the new guidelines, MD may have two performance obligations—delivering the units and "insuring" them while in transit. Revenue from the former would be recognized when control of the medical devices transfers to the distributor, presumably at shipment. Revenue from the latter would be recognized over time. Again, more facts would be required to conclude. Note that a subsequent amendment to Topic 606 permits companies to elect an accounting policy to treat the "insurance services" in this example as a cost of fulfilling the contract. Electing this policy would result in MD recognizing 100 percent of the revenue at shipment, while simultaneously recording an accrual for the expected costs of the "insurance services."

Third, many companies today use the sell-through method of revenue recognition for new product launches. This method recognizes that the fee for the new product may not be fixed or determinable because it's difficult to forecast future product returns or because the company has incentivized the customer with special privileges like price protection.

Under the new revenue rules in Topic 606, MD wouldn't be allowed to recognize revenue under a sell-through method. Instead, revenue would be recognized when control over the devices has transferred to the customer. Any pricing uncertainties would be considered in the transaction price—the amount of revenue reported, for example.

Fourth, MD must determine how to account for the commissions paid to its sales lead. Under current GAAP, there's diversity in practice. Some companies expense commissions as incurred, while others defer and amortize. But under the new rules, if the contract will be fulfilled over more than a year, the commissions must be deferred and amortized on a systematic basis consistent with the pattern in which revenue's being recognized. This will involve judgment. If the contract will be completed in 12 months or less, commissions may be expensed as incurred, at MD's election.

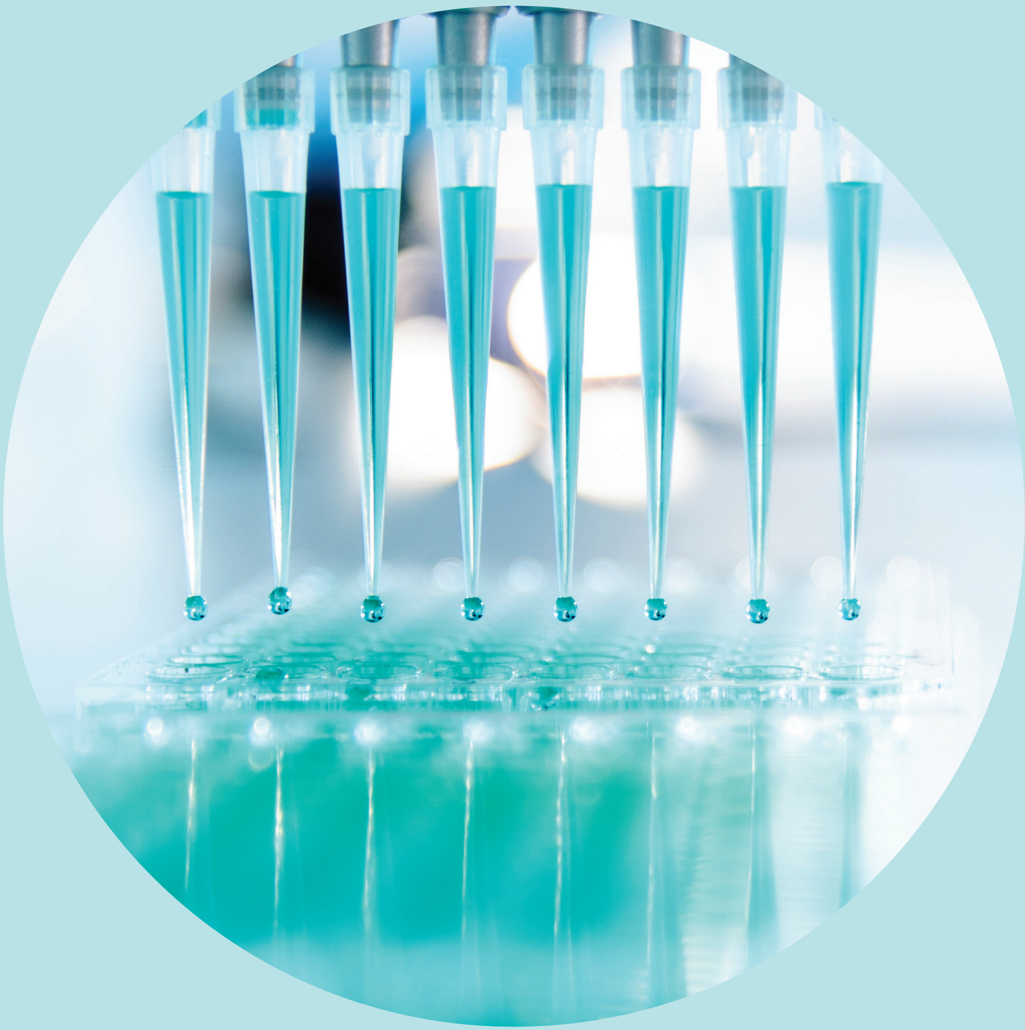
And finally, MD must evaluate how to account for the plant reconfiguration costs. Under current GAAP, there's diversity in practice here too. But under the new rules these costs would be deferred and amortized if they were necessary to fulfill the sales contract and presuming they weren't specifically addressed by other accounting literature.

FASB'S BIG REACH

In addition to introducing the new revenue recognition rules in Topic 606, the FASB took opportunity to improve GAAP in the following areas:

Companies now have more specific guidance on when to recognize gains and losses from sales of certain assets, such as equipment (ASC Subtopic 610-20).

New ASC Subtopic 340-40 provides welcome guidelines on how to account for costs of obtaining and fulfilling a contract.



Transition Checklist

It's critical to begin evaluating how the new rules will affect your business, from both an accounting and operational perspective. A number of steps ideally should be completed before the end of this year, or else it will be difficult to make the proper transition when the rules do become effective.

The steps include:

STEP 1

Read the new guidelines if you're on the finance team. At 1,000 pages, it will take time to familiarize yourself with the new guidance.

STEP 2

Run current revenue transactions through the new five-step revenue model. In some cases, contractual arrangements will be accounted for in the same way as current GAAP, albeit for different reasons. In other instances, the timing or amount of revenue recognition will change, sometimes dramatically.

STEP 3

Discuss any gray areas with your accounting advisor and consult your tax advisor to address the tax implications of the new guidelines. In perhaps more than a few cases, it will be unclear how to apply the principles in the new revenue guidance to a given transaction.

STEP 4

Communicate the expected effects of adopting the new guidelines to key stakeholders, including management, investors, and creditors.

STEP 5

Draft disclosure of the potential effects of adopting the new revenue guidelines for inclusion in SEC filings or other financial statements.

STEP 6

Identify whether the new rules will negatively affect debt covenants. If so, begin negotiating amendments or waivers with lenders.

STEP 7

Consider whether any commercial practices should change.

STEP 8

Begin planning for other operational changes.

Choose your Transition Method

This is an important transition decision that companies should think about one, two, or even three years prior to adoption because it will drive the nature, timing, and extent of any necessary systems and process changes.

Companies may adopt the new rules one of two ways:

- **Full retrospective basis**
- **Modified retrospective basis**

Either way, data for at least some contracts will need to be tracked for periods prior to the adoption date—that is, from 2016 or even earlier depending on the inception date of the contract. This means every company should decide as soon as possible which method it will use to transition to the new rules so that it can properly assess transactions that may be impacted by adoption of the new guidelines.

Full Retrospective

Companies that elect full retrospective adoption will almost certainly want systems in place well before ASC 606 becomes effective to track how revenue will be recognized under the new rules for all outstanding contracts, even while continuing to report under current GAAP rules until the date of adoption.

Modified Retrospective

Even companies that will transition using the modified retrospective basis should begin the arduous process of updating systems to track new performance obligations, estimates of variable consideration, and other data necessary to comply with the extensive disclosures required under the new rules.

The selection of a transition method is also important because it can affect reported trends, perhaps in surprising ways.

Software Revenue Transition Case Study

Life sciences companies should consider the implications of the new guidance for software-related revenue.

To demonstrate, assume that on December 31, 2017, a calendar-year-end publicly traded software developer delivers a software license, together with three years of PCS, for $12 million. On a relative stand-alone selling price basis, the license would be allocated $9 million of the arrangement price and the PCS would be allocated the remaining $3 million.

However, assume there's no VSOE of the fair value of the PCS. Under current GAAP, no revenue would be recognized during 2017 and the entire license fee would be recorded over the three-year PCS period, or $4 million per year beginning in 2018. Under the new revenue rules, $9 million in revenue would be recognized in 2017 upon delivery of the software license and the balance would be spread over the PCS period.

What does this all mean?

If the software developer adopts Topic 606 on January 1, 2018, using a modified retrospective adoption approach, $9 million of revenue would disappear. Why? For starters, under a modified retrospective transition approach, past periods aren't restated. Even in the 2018 financial statements, the comparative 2017 accounting period wouldn't show any revenue related to this software license because this is reflective of how current US GAAP would account for the transaction.

Upon adoption of the new rules, the software developer will book a catch-up entry to January 1, 2018, retained earnings for the difference between the revenue that would have been recognized under the new rules in 2017 ($9 million) versus what had been reported previously ($0). The software developer would book a $9 million adjustment to opening retained earnings, removing this amount from deferred revenue upon transition. Accordingly, $9 million of revenue never gets reported, which is difficult to explain to shareholders and other financial statement users.

WE'RE HERE TO HELP

Adopting the new revenue recognition guidelines is a significant undertaking that will involve more than just your company's finance and controllership teams. There are important tax, legal, and commercial considerations as well.

If you'd like to learn more, contact your Moss Adams professional or visit **www.mossadams.com/lifesciences**. You can also subscribe to have relevant articles, news, and event notifications sent to you via email.

About Our Life Sciences & Medical Devices Practice

Life sciences and medical devices companies face a unique set of operational and financial challenges, from conducting clinical trials to bringing products to market to expanding operations—all within a complex regulatory environment. How do successful businesses overcome these hurdles? It starts with seeking out the right mix of industry-specific accounting, tax, and consulting expertise. Our integrated service approach provides our clients with functional expertise, industry knowledge, and specialized services to help them overcome financial challenges and take advantage of valuable opportunities.

Thank you to Scott Ehrlich, who started Mind the GAAP in 2002, for his contributions to this guide.

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