New revenue guidance
Implementation in the pharmaceutical and life sciences sector

At a glance

Public companies must adopt the new revenue standards in 2018. Almost all companies will be affected to some extent by the new guidance, though the effect will vary depending on industry and current accounting practices. Although originally issued as a converged standard, the FASB and IASB have made slightly different amendments, so the ultimate application of the guidance could differ under US GAAP and IFRS.

The Revenue Recognition Transition Resource Group (TRG) has discussed various implementation issues impacting companies across many industries. These discussions may provide helpful insight into application of the guidance and the SEC expects registrants to consider these discussions in applying the new guidance.

This publication reflects the implementation developments over the past few years and highlights certain challenges specific to companies in the pharmaceutical and life sciences industry. The content in this publication should be considered together with our global Revenue guide, available at CFOdirect.com.

Overview

The pharmaceutical and life sciences industry includes a number of sub-sectors, the largest being pharmaceuticals, biotechnology, contract research organizations, and medical devices. The common feature is that each sub-sector develops, produces, and markets a diverse array of products, technologies, and services that relate to human health. Revenue recognition issues arise not only from the sale of drugs and medical devices, but increasingly from arrangements between companies in the industry to develop and bring products to market. Companies in the pharmaceutical and life sciences industry often enter into arrangements to develop drugs, either as a supplier of services, a consumer of those services, or through execution of license arrangements. These complex transactions are accounted for under the revenue standards (ASC 606 and IFRS 15, Revenue from contracts with customers).

This publication focuses on how the revenue standards will impact companies in the pharmaceutical and life sciences industry and contrasts the guidance with current practice under US GAAP and IFRS. The examples and related discussions are intended to provide areas of focus to assist companies in evaluating the implications of the revenue standards.
Scope

While certain contracts are scoped out of the revenue standards (e.g., lease contracts, insurance contracts, financial instruments, guarantees excluding warranties, certain non-monetary exchanges), the revenue standards apply to just about all contracts with customers. A customer is defined as a party that has contracted with a company to obtain goods or services that are an output of the company’s ordinary activities in exchange for consideration. The revenue standards do not apply to contracts when the parties participate in an activity or process (such as developing an asset in a collaboration agreement) and both parties share in the significant risks and benefits that result from the activity or process.

One challenge for companies in the pharmaceutical and life sciences industry will be evaluating their collaboration arrangements to determine if they represent contracts with customers. A contract to develop a product with a collaborator or partner with shared risks and benefits may be outside the scope of the revenue standards because that type of arrangement is not for the sale of goods or services that are an output of the company’s ordinary activities. For example, an agreement between a biotechnology company and pharmaceutical company to share equally in the significant risks and benefits associated with development of a specific drug is likely not in the scope of the revenue standards if the parties have a collaborative relationship rather than a vendor-customer relationship. If, however, the substance of the arrangement is that the biotechnology company is licensing its intellectual property (IP) or selling its compound to the pharmaceutical company and/or providing research and development (R&D) services, it will likely be in scope if such activities result in a good or service that is an output of the biotechnology company's ordinary activities.

Determining whether an arrangement is in the scope of the revenue standards can be complex. Arrangements may contain elements of both a customer and collaborator relationship. When analyzing arrangements, companies should identify the activities of the parties, understand the risks and benefits resulting from the activities, and determine if the parties are sharing in those risks and benefits. It will also be important to determine which party receives goods or services and whether those goods or services represent an output of the ordinary activities of the delivering party. If such arrangements (or certain obligations in these arrangements) are outside the scope of the revenue standards, the related income might not meet the definition of revenue, but instead be recorded as other income or in some cases, contra-expense.

For contracts that include some components that are in the scope of the revenue standards and other components that are in the scope of other standards, such as collaboration arrangements, a company will first apply the separation and/or measurement guidance in the other standards, if any. The transaction price will be reduced by the portion subject to the other standards and the revenue standards will apply to the remaining transaction price. For example, a company might lease a medical device to its customer and also provide related training services and consumables. In this arrangement, the lease would be subject to lease accounting while the training services and consumables may be subject to the revenue standards.

(1) Identify the contract  (2) Identify performance obligations  (3) Determine transaction price  (4) Allocate transaction price  (5) Recognize revenue  Licenses and other considerations

1. Identify the contract

A contract can be written, oral, or implied by a company’s customary business practices. Generally, any agreement with a customer that creates legally-enforceable rights and obligations meets the definition of a contract. Legal enforceability depends on the interpretation of the law and could vary across legal jurisdictions when the rights of the parties are not necessarily enforced in the same way.

Companies in the pharmaceutical and life sciences industry should consider any history of entering into amendments or side agreements to a contract that either change the terms of, or add to, the rights and obligations of a contract. These can be verbal or written, and could include cancellation, termination, or other provisions. They could also provide customers with options or discounts or change the substance of the arrangement. All of these have implications for
revenue recognition. Therefore, understanding the entire contract, including any amendments, is important to the accounting conclusion.

As part of identifying the contract, companies are required to assess whether collection of the consideration is probable, which is generally interpreted as a 75-80% likelihood in US GAAP and a greater than 50% likelihood in IFRS. This assessment is made after considering any price concessions expected to be provided to the customer. In other words, price concessions are variable consideration (which affects the transaction price), rather than a factor to consider in assessing collectibility. Further, the FASB clarified in an amendment of ASC 606 that companies should consider, as part of the collectibility assessment, their ability to mitigate their exposure to credit risk, for example, by ceasing to provide goods or services in the event of non-payment. The IASB did not amend IFRS 15 on this point, but did include additional discussion regarding credit risk in the Basis for Conclusions of their amendments to IFRS 15, which is likely to result in the same answer under both revenue standards.

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<tr>
<th>New standards</th>
<th>Current US GAAP</th>
<th>Current IFRS</th>
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<tr>
<td>A company will account for a contract with a customer when:</td>
<td>A company is prohibited from recognizing revenue from an arrangement until persuasive evidence of it exists, even if the other revenue recognition criteria have been met. Evidence of the arrangement should be consistent with the vendor’s customary business practices. If the vendor customarily obtains a written contract, a contract signed by both parties is the only acceptable evidence that the agreement exists. If the vendor does not customarily obtain a signed contract, the vendor must have other forms of evidence documenting that an arrangement exists (such as a purchase order, online authorization, and electronic communication or credit card authorization). Revenue from an arrangement is deferred in its entirety if a company cannot conclude that collection from the customer is reasonably assured.</td>
<td>A company is required to consider the underlying substance and economics of an arrangement, not merely its legal form. A company must establish that it is probable that the economic benefits of the transaction will flow to the company before it can recognize revenue.</td>
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| • The parties have approved the contract; | • Each party’s rights to goods or services to be transferred can be identified; | • The payment terms are defined;  
• The contract has commercial substance; and  
• It is probable the company will collect substantially all of the consideration. |
| The assessment of whether an amount is probable of being collected is made after considering any price concessions expected to be provided to the customer. Management should first determine whether it expects the company to accept a lower amount of consideration from the customer than the customer is obligated to pay, then determine if the remaining amount is collectible. If management concludes that collection is not probable, the arrangement is not accounted for using the five-step model. In that case, the company will only recognize consideration received as revenue when one of the following events occurs: | |  
• There are no remaining obligations to transfer goods or services to the customer and substantially all of the consideration has been received and is nonrefundable.  
• The contract has been terminated, and the consideration received is |
New standards

<table>
<thead>
<tr>
<th>Current US GAAP</th>
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<td>nonrefundable.</td>
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<td>• The company transferred control of the goods or services, the company stopped transferring goods or services to the customer (if applicable) and has no obligation to transfer additional goods or services, and the consideration received from the customer is nonrefundable [US GAAP only].</td>
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**Collectibility**

The collectibility threshold is not expected to significantly change current practice. A company will assess whether collection of the transaction price is probable under both US GAAP and IFRS, and, if it is, the company will recognize revenue as the performance obligations are satisfied, similar to today’s practice. If, at contract inception, a company concludes that collectibility of the transaction price is not probable, then a contract does not yet exist.\(^1\) Initial and subsequent impairment of customer receivables, to the extent material, will be presented separately below gross margin as an expense. This expense will be separately presented on the face of the income statement if it is material.

**Example 1-1 – Assessing collectibility with a history of price concessions**

**Facts:** Pharma sells prescription drugs to a government entity for $5 million. Pharma has historically experienced long delays in payment for sales to this entity. Pharma has sold prescription drugs to this entity for the last five years and continues to sell prescription drugs at its normal market price. In the past, Pharma has ultimately been paid, but only after agreeing to significant price concessions. Based on historical experience, Pharma expects to issue a price concession of $3 million on this contract.

How should Pharma account for the $5 million sale to the government entity?

**Analysis:** Pharma will need to evaluate its contract with the government entity at the inception of the arrangement to determine if it is probable that it will collect the amounts to which it is entitled in exchange for the prescription drugs. The revenue standards indicate that for purposes of determining the transaction price, the company should consider the variable consideration guidance, including the possibility of price concessions.

As a result of the expected price concession, the transaction price would be $2 million. Pharma would then evaluate whether it is probable that it will collect the adjusted transaction price in order to determine whether there is a contract. Assuming the collectibility hurdle is met, the transaction price would be recognized as Pharma satisfies its performance obligation of delivering the drug. Pharma would also need to determine if there is a significant financing component embedded in the arrangement if the company expects to receive the transaction price on a delayed basis.

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\(^1\) The revenue standards include examples illustrating collectibility assessments and evaluation of whether there is an implicit price concession resulting in the transaction price not being equal to the stated price.

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2. **Identify performance obligations**

Many companies within the pharmaceutical and life sciences industry provide multiple products or services to their customers as part of a single arrangement. For example, medical device companies often transfer equipment with consumables and also perform installation, training, or other maintenance services. Contract research organizations offer a broad array of services that enable a customer to outsource parts or all of its clinical trial process. Companies
must identify the separate performance obligations in an arrangement based on the terms of the contract and the company’s customary business practices. A bundle of goods and services might be accounted for as a single performance obligation in certain fact patterns.

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<th>New standards</th>
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<td>A performance obligation is a promise in a contract to transfer to a customer either:</td>
<td>The following criteria are applied to transactions to determine if elements included in a multiple-element arrangement should be accounted for separately:</td>
<td>The revenue recognition criteria are usually applied separately to each transaction. In certain circumstances, it might be necessary to separate a transaction into identifiable components to reflect the substance of the transaction. Two or more transactions might need to be grouped together when they are linked in such a way that the commercial effect cannot be understood without reference to the series of transactions as a whole.</td>
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<td>● A good or service (or a bundle of goods or services) that is distinct; or ● A series of distinct goods or services that are substantially the same and that have the same pattern of transfer to the customer.</td>
<td>● The delivered item has value to the customer on a standalone basis. ● If a general return right exists for the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the vendor.</td>
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<td>A good or service is distinct if both of the following criteria are met:</td>
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<td>● 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 (capable of being distinct). ● The good or service is separately identifiable from other goods or services in the contract (distinct in the context of the contract).</td>
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<td>Factors that indicate that two or more promises to transfer goods or services to a customer are not separately identifiable include (but are not limited to):</td>
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<td>a. The company provides a significant service of integrating the goods or services with other goods or services promised in the contract. b. One or more of the goods or services significantly modifies or customizes the other goods or services. c. The goods or services are highly interdependent or highly interrelated.</td>
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<td>ASC 606 states that a company is not required to separately account for promised goods or services that are immaterial in the context of the contract. IFRS 15 does not include the same specific guidance; however, IFRS reporters should consider materiality when identifying performance obligations.</td>
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Assessing whether goods and services are capable of being distinct is similar to determining if deliverables have standalone value under existing US GAAP or are separate components under existing IFRS, although the definitions are not identical. Under the new guidance, management will assess if the customer can benefit from the good or service with “resources that are readily available to the customer,” which could be a good or service sold separately by the company or another company, or a good or service the customer has already obtained.

Companies will need to determine whether the nature of the promise, within the context of the contract, is to transfer each of those goods or services individually or, instead, to transfer a combined item to which the promised goods or services are inputs. This will be a new assessment for companies as compared to today.

**Installation of equipment**

Medical device companies often provide installation services upon the placement of equipment at the customer’s location. These installation services range from activities that are basic or routine in nature to activities that substantially customize or modify the placed equipment. The nature of the services impact the determination as to whether installation is a separate performance obligation from the equipment itself.

There are generally two performance obligations in arrangements for which the placed equipment is operational without any customization or modification and the installation required is not complex. In these cases, the customer can benefit from the equipment on its own or with other readily available resources. The promises are separately identifiable because the equipment and installation services are not inputs into a combined item for which the customer has contracted. In other words, the vendor can fulfill its promise to transfer each promise independently and does not provide any significant integration, modification, or customization services.

Conversely, there is generally one performance obligation if the equipment is not operational without installation services that customize or modify the equipment. In these instances, the equipment and installation services may be considered inputs into a combined item for which the customer has contracted.

Promises within a contract should not be combined solely because one of the goods or services would not have been purchased without the others. For example, a contract that includes delivery of equipment and routine installation is not necessarily a single performance obligation even though the customer would not purchase the installation if it had not purchased the equipment.

Similarly, contractual requirements to use a particular vendor’s installation service does not impact the evaluation of whether the service is distinct from the equipment or other promises in an arrangement.

Refer to the *Licenses of intellectual property* section for additional information and examples of distinct promises in licensing arrangements.

**Customer options that provide a material right**

An option that provides a customer with free or discounted goods or services in the future might be a material right. A material right is a promise embedded in the current contract that should be accounted for as a separate performance obligation. If the option provides a material right to the customer, the customer, in effect, pays the company in advance for future goods or services, and the company recognizes revenue when those future goods or services are transferred or when the option expires.

An option to purchase additional goods or services at their standalone selling prices is a marketing offer and, therefore, not a material right. This is true regardless of whether the customer obtained the option only as a result of entering into the current transaction. An option to purchase additional goods or services in the future at a current standalone selling price could be a material right if prices are expected to increase. This is because the customer is being offered a discount on future goods or services compared to what others would have to pay as a result of entering into the current transaction.

**Example 2–1 – Options for additional goods or services**

**Facts:** MedTech enters into an arrangement for the sale of surgical instruments to Hospital. In conjunction with the sale, MedTech provides Hospital an option to purchase consumables for use with the surgical instruments for a one-year period at their standalone selling prices. Standalone selling price for the consumables is not expected to increase for the next two years. The consumables are needed to operate the surgical instrument, and MedTech is the only company that provides these consumables. In addition, MedTech offers to Hospital the option to purchase a different
surgical instrument at 40% off list price. Other comparable customers are typically provided a discount of 10% off list price. The option to purchase this instrument expires two years from executing this agreement. How should MedTech evaluate Hospital’s option to purchase consumables and the additional surgical instrument?

**Analysis:** At contract inception, MedTech should not account for the option to purchase consumables as a performance obligation as the option does not represent a material right (because the price offered to Hospital represents standalone selling price that is not expected to increase during the option term). The fact that the consumables are needed to operate the surgical instrument and MedTech is the only company that sells these consumables does not impact this assessment. In other words, unless the subsequent purchases are enforceable by law or represent a material right, they are not part of the initial contract regardless of the probability that the customer will make them. Therefore, MedTech would account for each of Hospital’s purchases of consumables as a separate performance obligation if and when Hospital exercises the option to purchase these goods.

The option to transfer the additional instrument at a significantly discounted price represents a material right to Hospital; therefore, this option should be accounted for as a separate performance obligation at contract inception. Because all comparable customers receive a 10% discount on the instrument during the same timeframe, the standalone selling price of the material right should be based on the incremental 30% discount offered to Hospital in the contract. MedTech should adjust the standalone selling price for the likelihood that Hospital will exercise the option (i.e., “breakage”). The amount of the transaction price allocated to the material right would be recognized as revenue when the additional instrument is purchased or when the option expires (that is, after the two year period).

**Example 2-2 – Free goods**

**Facts:** Pharma sells a drug in Country A subject to reimbursement through Country A’s government healthcare system. A $50 million cap on reimbursed sales to public (government-managed) hospitals was established at the outset of sales in 2017 in negotiation with the government, which represents 50,000 expected unit sales at the agreed-upon unit price of $1,000. Upon exceeding this 50,000 unit cap, Pharma would be required to provide any incremental units for the remainder of the year at no charge (i.e., no reimbursement from the government).

How should Pharma record unit sales during 2017 under the revenue standards?

**Analysis:** The ability to receive incremental “free” units would constitute a material right. As a material right, Pharma would conclude that the contractual arrangement entered into with the government on behalf of eligible patients offers significant discounts on future purchases (in this case, free product for units above the 50,000 unit cap) that would not be available without having entered into the contractual arrangement with the government. At contract inception, Pharma must first estimate the amount of “free” units and then allocate and defer a portion of the transaction price to the “free” product. The deferred portion would be recognized as revenue whenever those additional units are transferred or when the material right expires, if unexercised.

### 3. Determine transaction price

The transaction price is the consideration a vendor expects to be entitled to in exchange for satisfying its performance obligations in an arrangement. Determining the transaction price is straightforward when the contract price is fixed, but is more complex when the arrangement includes a variable amount of consideration.

Variable consideration includes payments in the form of milestone payments, royalties, rebates, price protection, performance bonuses, and other discounts and incentives. Common examples of arrangements with variable consideration in the pharmaceutical and life sciences industry include licensing arrangements with development-based and/or sales-based milestone payments and sales-based royalties (discussed further below), and distribution arrangements with rebates, price protection, returns provisions, or other incentives provided to or available from wholesalers, retailers, and end customers.
If the promised amount of consideration in a contract is variable, a company should estimate the total transaction price. This estimate can be based on either the expected value (probability-weighted estimate) or the most likely amount of consideration expected from the transaction, whichever is more predictive. The estimated transaction price should be updated at each reporting date to reflect the current facts and circumstances.

In general, with the exception of sales- or usage-based royalties in exchange for intellectual property (discussed further below), the estimate of variable consideration is subject to a constraint. The objective of the constraint is for a company to include in the transaction price some or all of an amount of variable consideration only to the extent that it is probable (US GAAP) or highly probable (IFRS) 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. Such a reversal would occur if there is a significant downward adjustment of the cumulative amount of revenue recognized for a specific performance obligation.

Companies will need to apply judgment to determine if variable consideration is subject to a significant reversal. The following indicators might suggest that variable consideration could result in a significant reversal of cumulative revenue recognized in the future:

- The amount of consideration is highly susceptible to factors outside the influence of the company. Those factors may include volatility in the market, the judgment or actions of third parties (e.g., regulatory approval of a drug compound), the successful outcome of a clinical trial, and a high risk of obsolescence of the promised good or service.
- Resolution of the uncertainty about the amount of consideration is not expected for a long period of time.
- The company has limited experience with similar types of contracts or that experience has limited predictive value.
- The company 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.
- The contract has a large number and broad range of possible consideration amounts.

Companies will need to determine if there is a portion of the variable consideration (i.e., a minimum amount) that will not result in a significant revenue reversal. That amount will be included in the estimated transaction price. The estimate will be reassessed each reporting period, including any estimated minimum amounts.

Consideration payable to a customer, right of return, noncash consideration, and significant financing components are other important concepts to consider in determining the transaction price.

**Rebates, price protection, and other discounts and incentives**

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<tr>
<td>Rebates, price protection, concessions, and other discounts and incentives are types of variable consideration. Therefore, the consideration will be estimated and included in the transaction price based on either the expected value (probability-weighted estimate) or most likely amount approach if it is probable (US GAAP) or highly probable (IFRS) that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The transaction price should include any minimum amount of variable consideration not subject to significant reversal, even if the entire</td>
<td>The seller's price must be fixed or determinable for revenue to be recognized. Rebates, price protection clauses, and other discounts and incentives must be analyzed to conclude whether all of the revenue from the current transaction is fixed or determinable. Rebates or refunds are recognized on a systematic and rational basis. Measurement of the total rebate or refund obligation is based on the estimated number of purchases that the customer will ultimately make under the arrangement. If the rebate or incentive payment cannot be reasonably estimated, a liability is recognized for the maximum potential refund or rebate.</td>
<td>Revenue is measured at the fair value of the consideration received or receivable. Fair value is the amount an asset could be exchanged for, or a liability settled, between knowledgeable, willing parties in an arm's length transaction. Trade discounts, volume rebates, and other incentives (such as cash settlement discounts or government claw-backs) are taken into account in measuring the fair value of the consideration to be received. Revenue related to variable consideration is recognized when it is probable that the economic benefits will flow to the company and the amount is reliably measurable, assuming all other revenue recognition criteria are met.</td>
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Companies in the pharmaceutical and life sciences industry likely already consider the impact of rebates, price protection, and other concessions on revenue recognition. Companies might see some changes to their accounting and processes related to rebates or concessions as estimates are required to be made upfront when determining the transaction price. Other changes include those situations when companies did not recognize revenue because the price was not fixed or determinable. Under the revenue standards, these companies might recognize revenue earlier if there is a minimum amount of variable consideration that is not subject to significant reversal in the future.

**Example 3-1 – Estimating rebates to a customer**

**Facts:** MedTech enters into an arrangement to sell a product to a customer. At the end of each year, the customer is entitled to a rebate on its annual purchases whereby the price per unit is retrospectively reduced based on achievement of specific purchasing levels. MedTech has determined based on its experience with similar contracts that it is probable (US GAAP) or highly probable (IFRS) that including an estimate of variable consideration will not result in a significant reversal of cumulative revenue recognized in the future. The estimated amount of the rebate is determined based on the number of units purchased during the year as follows:

<table>
<thead>
<tr>
<th>Units purchased</th>
<th>Per unit rebate</th>
<th>Expected probability</th>
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<tbody>
<tr>
<td>0 – 100,000</td>
<td>10%</td>
<td>80%</td>
</tr>
<tr>
<td>100,000 – 500,000</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>500,000+</td>
<td>20%</td>
<td>5%</td>
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</table>

How should MedTech account for the potential rebate to the customer?

**Analysis:** Since the rebate has retrospective implications on the per unit price, the consideration in the contract is considered variable at contract inception. MedTech should estimate the amount of the rebate using an expected value (probability-weighted estimate) or most likely outcome approach, whichever is more predictive. A probability-weighted estimate would result in a rebate of approximately 11% ((10% x 80%) + (15% x 15%) + (20% x 5%)). The most-likely outcome approach would result in an estimated rebate of 10%. If MedTech is unsure whether the estimated amount will result in a significant reversal of revenue, the company should only include in the transaction price an amount that is probable (US GAAP) or highly probable (IFRS) of not resulting in a significant reversal of cumulative revenue recognized (i.e., a minimum amount).

**Example 3-2 – Retroactive payback provisions**

**Facts:** Companies that operate in the medical device industry in Country A are required to make payments to Country A’s government health system equal to a stated percentage of domestic industry sales that exceed regional maximum ceilings (caps) in a given year. If triggered, the portion of the payback provision allocable to a particular company is based on that company’s current market share relative to the medical device industry as a whole.

The industry-wide payback amount in 2017 may not exceed 50% of sales in excess of the regional maximum ceiling. A regional maximum ceiling of $500 million was implemented for all medical device sales in Country A during 2017.

MedTech expects to sell $200 million of medical devices in Country A during 2017 and, based on historical industry performance and other available data, expects that total industry sales of medical devices will approximate $800 million for the year.

Therefore, MedTech’s obligation is estimated to be $37.5 million for the year, which is calculated as MedTech’s 25% estimated market share ($200 million/$800 million) multiplied by the excess industry sales subject to the payback provision (50% x ($800 million - $500 million)).

How should MedTech record unit sales in 2017?

**Analysis:** The amount due under the payback provision would be accounted for as a retroactive rebate (i.e., variable consideration).
MedTech would estimate its portion of the payback at the beginning of the year, likely using the expected value approach due to the range of possible outcomes in this fact pattern. MedTech would include the variable consideration in the transaction price to the extent it is probable (US GAAP) or highly probable (IFRS) that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved. If MedTech concluded that it could not estimate the variable consideration to identify a minimum amount, it would constrain the full amount of the potential payment (i.e., 50% of each sale made in 2017) until it is able to estimate such an amount. Assuming the variable consideration constraint could be overcome, MedTech would reflect each sale during 2017 at a discount of 18.75%, such that by the end of the year, it would have accrued a refund liability to the government health system of $37.5 million.

Medicare Part D coverage gap

The Medicare Part D Coverage Gap ("coverage gap" or "donut hole") is a government program under the Patient Protection and Affordable Care Act (PPACA) in which all pharmaceutical drug manufacturers are responsible for paying 50% of the cost of their branded drugs when a patient falls within the coverage gap during a calendar year. While in the coverage gap, a patient temporarily loses Medicare Part D insurance coverage on prescription drugs based on annual drug costs incurred by that patient and, therefore, must pay for a portion of the drugs out-of-pocket. Under the PPACA, while patients are in the coverage gap, pharmaceutical manufacturers are required to provide discounted products to eligible Medicare beneficiaries receiving covered Part D drugs to alleviate the out-of-pocket cost burden on the patient.

Under existing practice, companies make a policy election between two acceptable methods – a “spreading” approach or a “point-of-sale” approach (sometimes referred to as a “specific identification” approach). Under the spreading method, the estimated impact of the rebate expected to be incurred for the annual period is recognized ratably using an estimated, effective rebate rate for all of a company’s projected sales to Medicare patients throughout the year. Under the point-of-sale method, the rebate is recognized at the time a company delivers the drug to the patient, such that by the end of the year, the Medicare Part D coverage gap subsidies, primarily enter and exit the Medicare coverage gap in the third and fourth quarters.

Under the new guidance, we believe those same two approaches will generally continue to be supportable noting the following:

- The revenue standards introduce the concept of a “material right” (see prior discussion in Step 2). The “spreading” method appears to be broadly consistent with the accounting for an option (i.e., a material right) provided to a customer. Under this method, companies will 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 into revenue when the coverage gap subsidies are utilized. However, we are aware that in some cases, companies experience higher coverage gap liabilities earlier in the year (e.g., with certain more expensive drugs) with sales reverting back to list price in subsequent periods. In these cases, it would not be appropriate to follow a spreading approach that results in a contract asset on the balance sheet as that would, in effect, be inappropriately pulling revenue forward for optional purchases.
- Whichever method is applied would need to be applied on a consistent basis for similar arrangements.

Example 3-3 – Medicare Part D coverage gap

Facts: Pharma currently has one marketed product that is impacted by the Medicare coverage gap provision. Gross revenue of $500 million is earned every quarter. Pharma’s full year estimate of coverage gap subsidies (i.e., reimbursements to the Federal government) is $400 million. Pharma’s inventory does not sit in the channel at the end of a particular quarter (i.e., product sold in Q2 will be sold through to the end customer in Q2). Pharma’s customers primarily enter and exit the Medicare coverage gap in the third and fourth quarters. Pharma’s quarterly revenues, net of coverage gap subsidies, are as follows:

<table>
<thead>
<tr>
<th>In millions</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
<th>Total</th>
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<tbody>
<tr>
<td>Actual sales per quarter, net of subsidies</td>
<td>$500</td>
<td>$500</td>
<td>$250</td>
<td>$350</td>
<td>$1,600</td>
</tr>
<tr>
<td>Spread basis</td>
<td>$400</td>
<td>$400</td>
<td>$400</td>
<td>$400</td>
<td>$1,600</td>
</tr>
<tr>
<td>Quarterly difference</td>
<td>$100</td>
<td>$100</td>
<td>($150)</td>
<td>($50)</td>
<td>-</td>
</tr>
<tr>
<td>Cumulative year-to-date difference</td>
<td>$100</td>
<td>$200</td>
<td>$50</td>
<td>$0</td>
<td>-</td>
</tr>
</tbody>
</table>
How should Pharma account for its coverage gap obligations?

**Analysis:** If Pharma accounts for coverage gap subsidies as a material right, it would recognize a contract liability for $100, $200, and $50 at the end of Q1, Q2, and Q3, respectively. The contract liability, reflecting the material right in the arrangement (i.e., the discounted future product available from cumulative list price purchases to date), would fully reverse in Q4.

The contract liability would be calculated in accordance with the practical alternative provided in the revenue standards, which provides an election to include the total number of estimated drugs to be sold during the year in the initial measurement of the transaction price of each drug. In other words, all sales of drugs before, during, and after the incurrence of coverage gap liabilities would be priced at a discount to reflect the reduced transaction price for drugs sold during the period in which Pharma is liable to fund a portion of patient costs through this program.

If Pharma accounts for coverage gap subsidies using a specific identification approach, it would recognize the subsidies as a reduction of revenue in the periods they are incurred. Therefore, Pharma would record no reduction in revenue in either Q1 or Q2 and would instead reflect a reduction of revenue of $250 and $150 in Q3 and Q4, respectively.

**Consideration payable to a customer**

A company might pay, or expect to pay, consideration to its customer. The consideration paid can be cash, either in the form of rebates or upfront payments, or a credit or other incentive that reduces amounts owed to the company by a customer. Payments to customers can also be in the form of equity.

Management should consider whether payments to customers are related to a revenue contract even if the timing of the payment is not concurrent with a revenue transaction. Such payments could nonetheless be economically linked to a revenue contract; for example, the payment could represent a modification to the transaction price in a contract with a customer. Management will therefore need to apply judgment to identify payments to customers that are economically linked to a revenue contract.

An important step in this analysis is identifying the customer in the arrangement. Management will need to account for payments made directly to its customer, payments to another party that purchases the company’s goods or services from its customer (that is, a customer’s customer within the distribution chain), and payments to another party made on behalf of a customer pursuant to the arrangement between the company and its customer.

Consideration payable to a customer is recorded as a reduction of the arrangement’s transaction price, thereby reducing the amount of revenue recognized, unless the payment is for a distinct good or service received from the customer. If payment is for a distinct good or service, it would be accounted for in the same way the company accounts for other purchases from suppliers. Determining whether a payment is for a distinct good or service received from a customer requires judgment. A company might be paying a customer for a distinct good or service if the company is purchasing something from the customer that is normally sold by that customer.

Management also needs to assess whether the consideration it pays for distinct goods or services from its customer exceeds the fair value of those goods or services. Consideration paid in excess of fair value reduces the transaction price. It can be difficult to determine the fair value of the distinct goods or services received from the customer in some situations. A company that is not able to determine the fair value of the goods or services received should account for all of the consideration paid or payable to the customer as a reduction of the transaction price since it is unable to determine the portion of the payment that is a discount provided to the customer.

**Example 3-4 – Estimating rebates to indirect customers**

**Facts:** Pharma enters into an arrangement with Distributor for the sale of a drug. Distributor then sells the product to Retailer. Retailer is entitled to a sales rebate from Pharma of 25% of the sales price if Retailer purchases at least 1,000 units from Distributor in bulk (that is, in one transaction).

The unit selling price for each product is $100. Pharma believes that it has sufficient basis to estimate that Retailer will purchase the necessary 1,000 units to earn the rebate (i.e., Pharma has history and experience with the retail distribution channel and the buying patterns of Retailer with Distributor). Therefore, Pharma concludes that it is probable (US GAAP) or highly probable (IFRS) that a significant reversal in the amount of cumulative revenue recognized will not occur in the future.

How should Pharma account for rebates to be paid to the indirect customer?
**Analysis:** The performance obligation in the contract is the promise to deliver individual units of the drug to Distributor. To determine the transaction price, Pharma will need to estimate the effects of the bulk rebates offered to Retailer. That is, each time a shipment is ordered by Distributor, Pharma will need to estimate what portion of the shipment will be sold on to Retailer, who will buy in bulk and earn the rebate. The total estimated rebate would be a reduction from the contractual sales price in the transactions with Distributor.

Even though the product was sold to Distributor and the rebates are paid to Retailer, the classification of the payment is still a reduction of revenue on the basis that payments made by a company to its customer’s customer are assessed and accounted for the same as those paid directly to the company’s customer.

**Example 3-5 – Discounts provided to group purchasing organizations**

**Facts:** MedTech sells disposable medical products to hospitals through a network of distributors at list price. The company has agreements in place with various group purchasing organizations (GPOs) to give a discount of 20% to specific hospitals affiliated with these GPOs. When a GPO-affiliated hospital purchases the disposable medical products from a distributor, it purchases them at the discounted amount. The distributor then requests reimbursement by MedTech of the discounted amount. The company has some historical data related to the mix of sales to GPOs and non-GPOs; however, the range varies significantly from period to period.

How should MedTech account for GPO discounts?

**Analysis:** MedTech would estimate variable consideration, including the estimated discount to be paid on sales to GPO-affiliated hospitals. The amount of revenue recognized would be the amount that is probable (US GAAP) or highly probable (IFRS) of not resulting in a significant reversal of cumulative revenue in the future. Although the company’s history varies significantly, that history may indicate there is a minimum amount of revenue that can be recognized upon shipment of the product.

**Other considerations:** Companies will often pay administrative fees to GPOs (and not directly to the GPO member) to cover operating expenses or other services for its members. A question exists as to whether these administrative fees paid to the GPOs are classified as a reduction of revenue or as an operating expense.

In determining the accounting for the administrative fee paid to GPOs under the revenue standards, it is important to consider the relationships between the vendor, the GPO, and the GPO member in order to determine whether the GPO is a customer. Identifying the customer requires an evaluation of the substance of the relationship of all parties involved in the transaction. The following factors, if present, may indicate that the GPO is effectively an extension of the customer (that is, the GPO member) and, therefore, the GPO administrative fee should be recorded as a reduction of revenue:

- The GPO member is an owner, or partial owner, of the GPO; or
- There is a mechanism to “flow through” the administrative fee from the GPO to the GPO member.

**Noncash consideration**

Any noncash consideration received from a customer needs to be included in the transaction price and measured at fair value. The measurement date, however, may differ under US GAAP and IFRS. ASC 606 specifies that the measurement date for noncash consideration is contract inception, which is the date at which the criteria in Step 1 of the revenue model are met. Changes in the fair value of noncash consideration after contract inception are excluded from revenue. IFRS 15 does not include specific guidance on the measurement date of noncash consideration and therefore, different approaches may be acceptable. Management should also consider the accounting guidance for derivative instruments to determine whether an arrangement with a right to noncash consideration contains an embedded derivative.

**Significant financing component**

Pharmaceutical and life sciences companies should also be aware of the accounting impact of significant financing components, such as extended payment terms. If there is a difference between the timing of receiving consideration from the customer and the timing of the company’s performance, a significant financing component may exist in the arrangement.

The revenue standards require companies to impute interest income or expense and recognize it separately from revenue (as interest expense or interest income) when an arrangement includes a significant financing component. However, as a practical expedient, companies do not need to account for a significant financing component if the timing...
difference between payment and performance is less than one year. In certain circumstances, companies may also attribute a significant financing component to one or more, but not all, performance obligations in a contract.

Management should determine if payment terms are reflective of a significant financing component or if the difference in timing between payment and performance arises for reasons other financing. For example, the intent of the parties might be to secure the right to a specific product or service, or to ensure that the seller performs as specified under the contract, rather than to provide financing.

**Right of return**

Pharmaceutical, biotechnology, and certain medical device companies may sell products with a right of return. The right of return in pharmaceutical arrangements often permits customers to return product within a few months prior to and following product expiration. Return rights may also take on various other forms, such as trade-in agreements. These rights generally result from the buyer’s desire to mitigate the risk related to the products purchased and the seller’s desire to promote goodwill with its customers. The sale of goods with a right of return will be accounted for similar to current guidance, which results in revenue recognition for only those products when the company concludes it is probable (US GAAP) or highly probable (IFRS) that there is not a risk of significant revenue reversal in future periods under the variable consideration guidance.

Pharmaceutical companies usually destroy returned inventory, but certain medical device companies can resell returned product. The impact of product returns on earnings under the new guidance will be largely unchanged from current US GAAP and IFRS. However, the balance sheet will be grossed up to include the refund obligation and the asset for the right to the returned goods. The asset is assessed for impairment if indicators of impairment exist.

**Example 3-6 – Sale of product with a return right**

**Facts:** Pharma sells cardiac drugs through a number of wholesale and retail customers. The drugs have a shelf life of 24 months from the date manufactured. Both wholesalers and retailers can return the drugs from six months before to six months after the expiration date, subject to compliance with other provisions in Pharma’s return policy. Pharma has sold these drugs for the past two years. Through the end of the two years, 3% of the drugs sold to date have been returned in accordance with policy.

On December 31, Pharma sold 100 units to Distributor for $200 each, for a total sale of $20,000.

How should Pharma account for the return right?

**Analysis:** Pharma should not record revenue for the units that are anticipated to be returned (3% of the 100 units, or 3 units). Pharma should record a refund liability for 3 drug units and record an asset for the right to the drug units expected to be returned. The asset should be recorded at the original cost of the drug units. Pharma would not derecognize the refund liability and related asset until the refund occurs or the refund right lapses (although Pharma should adjust these amounts as it revises its estimate of returns over time). The asset will need to be assessed for impairment until derecognition. In many cases in pharmaceutical sales, the returned product may have limited to no value and, therefore, the asset may be immediately impaired.

The transaction price for the 97 drug units that Pharma believes will not be returned would be recorded as revenue when control transfers to the customer.

**Pay-for-performance arrangements**

Companies within the industry sometimes enter into pay-for-performance or risk-sharing contracts when pricing and incentives are based on outcomes or achievement of performance measures. Under current guidance, recognizing revenue at the time of sale for these types of arrangements may be appropriate if the company has sufficient historical evidence supporting its refund estimates. Companies may also defer recognition of revenue until the underlying contingency has resolved. Such contingencies represent a form of variable consideration in the revenue standards.

**Example 3-7 – Pay-for-performance arrangements**

**Facts:** Pharma manufactures and sells a drug to Hospital, which administers the drug to its patients. Under the terms of the arrangement, if patients’ test results do not meet the pre-determined objective criteria after a defined treatment period of three months, Hospital is eligible for a full refund of the administered product from Pharma.
Over the past two years, Pharma and Hospital have been tracking the number of patients whose post-treatment results did not meet the pre-determined criteria, and it has consistently ranged 6%–7% on a monthly and annual basis. It is expected that future results will be comparable to historical experience.

How should the vendor account for this arrangement?

*Analysis:* Pharma would need to estimate the total transaction price at contract inception, likely using the expected value method given the nature of the arrangement.

Given historical experience and the expectation that future results will be comparable to that experience, Pharma is likely to conclude that it has the ability to predict the number of patients who will benefit from the drug. Therefore, Pharma would include an amount of variable consideration in the transaction price that would not be subject to significant revenue reversal when the uncertainty is subsequently resolved.

### 4. Allocate transaction price

Pharmaceutical and life sciences companies often provide multiple products or services to their customers as part of a single arrangement. Under the revenue standards, they will need to allocate the transaction price to the separate performance obligations in one contract based on the relative standalone selling price of each separate performance obligation. There are certain exceptions when discounts or variable consideration relate specifically to one or more, but not all, of the performance obligations.

<table>
<thead>
<tr>
<th>New standards</th>
<th>Current US GAAP</th>
<th>Current IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>The transaction price is allocated to separate performance obligations based on the relative standalone selling price of the performance obligations in the contract. Companies will need to estimate the standalone selling price for items not sold separately. A residual approach may be used as a method to estimate the standalone selling price when the selling price for a good or service is highly variable or uncertain. Variable consideration or discounts might relate only to one or more, but not all, performance obligations in the contract. Variable consideration is allocated to specific performance obligations if both of the following criteria are met:</td>
<td>The consideration in an arrangement is allocated to the elements of a transaction based on the relative standalone selling price. The residual value method cannot be used (except for software companies). Allocation to a delivered item is limited to the consideration that is not contingent on providing an undelivered item or meeting future performance obligations (the “contingent revenue cap”).</td>
<td>Consideration is generally allocated to the separate components in the arrangement based on a relative fair value or cost plus a reasonable margin approach. A residual or reverse residual approach may also be used.</td>
</tr>
</tbody>
</table>
### New standards vs. Current US GAAP vs. Current IFRS

<table>
<thead>
<tr>
<th>New standards</th>
<th>Current US GAAP</th>
<th>Current IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>service (or to a specific outcome from satisfying the performance obligation or transferring the distinct good or service).</td>
<td></td>
<td></td>
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<tr>
<td>• The outcome is consistent with the allocation objective.</td>
<td></td>
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</tr>
<tr>
<td>A discount is allocated to a specific performance obligation if all of the following criteria are met:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The company regularly sells each distinct good or service on a standalone basis.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The company regularly sells, on a standalone basis, a bundle of some of those distinct goods or services at a discount.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The discount attributable to the bundle of distinct goods or services is substantially the same as the discount in the contract and observable evidence supports the discount belonging to that performance obligation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The basic allocation principle has not changed under the new guidance; however, there are three specific differences that could affect allocation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Currently, under US GAAP, the amount allocable to a delivered unit or units in a multiple element arrangement is limited to the amount that is not contingent on the delivery of additional units or meeting other specified performance conditions. There is no contingent revenue cap under the revenue standards, although variable consideration could be constrained.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• A company will allocate discounts and variable consideration amounts to specific performance obligations if certain criteria are met.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• The residual approach involves deducting from the total transaction price the sum of the observable standalone selling prices of other goods and services in the contract to estimate standalone selling prices for the remaining goods and services. This approach is an estimation methodology, not an allocation methodology like the residual method applied under current US GAAP and IFRS guidance. Under the revenue standards, the residual approach should only be used if the selling price of a good or service is highly variable or uncertain. Before utilizing this approach, management should first consider the overall principle that a company should maximize the use of observable data and should assess whether another method provides a reasonable method for estimating standalone selling price.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Contracts with multiple promises and minimum purchase commitments

Medical device companies often enter into contracts with hospitals and other medical providers to sell equipment, sell equipment-related consumables, and perform maintenance, training, or other services. Total consideration for these types of arrangements is typically based on a minimum purchase requirement for the equipment-related consumables, if such a requirement exists. Therefore, medical device companies must first identify each distinct promise in these arrangement and then allocate the arrangement consideration to each of those performance obligations.
Example 4-1 – Allocate the transaction price to performance obligations

Facts: Hospital contracts with MedTech to purchase medical equipment and a minimum of 4,500 consumables over a five-year period to be used in the operation of the equipment. The amount of consumables purchased by Hospital is unrelated to the usage of the medical equipment. In addition, MedTech will provide maintenance and training services. Hospital will pay MedTech $4.00 per consumable purchased.

MedTech determines that the arrangement has four performance obligations - the sale of medical equipment, sale of consumables, maintenance, and training. Contract consideration is $90,000 (4,500 consumables per year x 5 years x $4.00/unit). Any purchases above 4,500 units are optional and the purchase price for units above the minimum is not discounted for the usual stand-alone selling price (i.e., no material right exists). Therefore, the right to purchase excess units is not considered a separate performance obligation.

At the contract inception date, the standalone selling price of each performance obligation is as follows:

- Equipment: $15,000
- Consumables: $3.50 per unit
- Maintenance: $10,000
- Training: $5,000

How should MedTech allocate contract consideration among the performance obligations at contract inception?

Analysis: The $90,000 contract consideration would be allocated to the performance obligations based on their relative standalone selling prices at the inception of the contract, as follows:

<table>
<thead>
<tr>
<th>Performance obligation</th>
<th>Standalone selling price</th>
<th>Allocation %</th>
<th>Allocation of consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical equipment</td>
<td>$15,000</td>
<td>14%</td>
<td>$12,600</td>
</tr>
<tr>
<td>Consumables</td>
<td>78,750*</td>
<td>72%</td>
<td>64,800</td>
</tr>
<tr>
<td>Maintenance</td>
<td>10,000</td>
<td>9%</td>
<td>8,100</td>
</tr>
<tr>
<td>Training</td>
<td>5,000</td>
<td>5%</td>
<td>4,500</td>
</tr>
<tr>
<td>Total</td>
<td>$108,750</td>
<td>100%</td>
<td>$90,000</td>
</tr>
</tbody>
</table>

* 4,500 consumable units per year x 5 years x $3.50 standalone price per unit.

5. Recognize revenue

Pharmaceutical and life sciences companies often have contracts that include a service (e.g., installation) with the sale of goods (e.g., a medical device). Companies in the industry may also manufacture for and sell products to a customer that have no alternative use or perform clinical trial support services over a period of time. A performance obligation is satisfied and revenue is recognized when “control” of the promised good or service is transferred, either over time or at a point in time, to the customer. A customer obtains control of a good or service if it has the ability to (1) direct its use and (2) obtain substantially all of the remaining benefits from it. Directing the use of an asset refers to a customer’s right to deploy the asset, allow another company to deploy it, or restrict another company from using it. Management should evaluate transfer of control primarily from the customer’s perspective, which reduces the risk that revenue is recognized for activities that do not transfer control of a good or service to the customer.
<table>
<thead>
<tr>
<th>New standards</th>
<th>Current US GAAP</th>
<th>Current IFRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control refers to the ability to direct the use of and obtain substantially all of the remaining benefits (i.e., potential cash flows) from the asset. Control also includes the ability to prevent others from directing the use of, or obtaining benefits from, the asset. The benefits from an asset include, but are not limited to:</td>
<td>Revenue generally is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectibility is reasonable assured.</td>
<td>Revenue recognition occurs at the time of delivery, when the following conditions are satisfied:</td>
</tr>
<tr>
<td>- Using the asset to produce goods, provide services, enhance the value of others assets, settle liabilities, or reduce expenses</td>
<td>For services arrangements not within the scope of guidance for construction or certain production-type contracts, revenue is recognized using the proportional performance or completed performance model.</td>
<td>- The risks and rewards of ownership have transferred.</td>
</tr>
<tr>
<td>- Physical possession</td>
<td>For services arrangements in the scope of guidance for construction or certain production-type contracts, revenue is recognized using the percentage-of-completion method when reliable estimates are available.</td>
<td>- The seller does not retain managerial involvement to the extent normally associated with ownership nor retain effective control.</td>
</tr>
<tr>
<td>- Ability to pledge the asset to secure a loan, sell the asset, or exchange the asset.</td>
<td>The completed-contract method is required when reliable estimates cannot be made.</td>
<td>- The amount of revenue can be reliably measured.</td>
</tr>
<tr>
<td><strong>Over time revenue recognition</strong></td>
<td><strong>Point in time revenue recognition</strong></td>
<td>- It is probable that the economic benefit will flow to the customer.</td>
</tr>
<tr>
<td>A company transfers control of a good or service over time and, therefore, satisfies a performance obligation and recognizes revenue over time, if one of the following criteria is met:</td>
<td>A performance obligation is satisfied at a point in time if none of the criteria for satisfying a performance obligation over time are met. If the performance obligation is satisfied at a point in time, indicators of the transfer of control include:</td>
<td>- The costs incurred can be measured reliably.</td>
</tr>
<tr>
<td>- The customer simultaneously receives the benefits provided by the company’s performance as the company performs.</td>
<td>- The company has a right to payment for the asset.</td>
<td></td>
</tr>
<tr>
<td>- The company’s performance creates or enhances an asset that the customer controls as the asset is created.</td>
<td>- The customer has legal title to the asset.</td>
<td></td>
</tr>
<tr>
<td>- The company’s performance does not create an asset with an alternative use, and the company has an enforceable right to payment for performance completed to date.</td>
<td>- The company transferred physical possession of the asset.</td>
<td></td>
</tr>
<tr>
<td><strong>Point in time revenue recognition</strong></td>
<td><strong>Revenue recognition</strong></td>
<td>If these criteria are not met, revenue is recognized once the risks and rewards of ownership have transferred, which may be upon sale to an end customer.</td>
</tr>
<tr>
<td>A performance obligation is satisfied at a point in time if none of the criteria for satisfying a performance obligation over time are met.</td>
<td>For revenues arising from the rendering of services, provided that all of the following criteria are met, revenue should be recognized by reference to the stage of completion of the transaction at the balance sheet date (the percentage-of-completion method):</td>
<td>For revenues arising from the rendering of services should be recognized only to the extent of the expenses recognized that are recoverable (a “cost-recovery” approach).</td>
</tr>
</tbody>
</table>
New standards | Current US GAAP | Current IFRS
---|---|---
- The customer has significant risks and rewards of ownership.
- The customer has accepted the asset.

Companies that manufacture customized products and recognize revenue at a point in time under current guidance will need to assess the new criteria, including whether the product has no alternative use and whether they have a right to payment for performance completed to date. These companies could potentially change from point in time recognition under current guidance to over time recognition if the criteria are met.

The timing of revenue recognition for point-in-time arrangements could change (and be accelerated) for some companies compared to current guidance, which is more focused on the transfer of risks and rewards than the transfer of control. The transfer of risks and rewards is an indicator of whether control has transferred under the new guidance, but companies will also need to consider the other indicators in making this determination: the company has an enforceable right to payment, the customer has legal title, the customer has physical possession, and the customer has accepted the asset.

**Sales to distributors and consignment stock**

Some pharmaceutical and medical device companies recognize revenue using a “sell-through” approach. Under the sell-through approach, revenue is not recognized until the product is sold to the end customer, either because inventory is on consignment at distributors, hospitals, or others, or because the final selling price is not determinable until the product is sold to the end customer.

Under the new guidance, revenue is recognized upon the transfer of control to the customer. Companies that previously accounted for arrangements using a sell-through approach will need to consider at what point control has passed to the customer based on the indicators provided in the revenue standards, which could impact the timing of revenue recognition.

The revenue standards require a company that has entered into a consignment stock arrangement with its customer to assess when control transfers to that customer. In the pharmaceutical and life sciences industry, the customer could be a distributor, hospital, or another company. If the customer has control of the product, including the right (but not the obligation) to return the product to the seller at its discretion and the customer does not have a significant economic incentive to exercise that right, control transfers when the product is delivered to the customer. The company would evaluate the return right as variable consideration. This might result in earlier revenue recognition than under current standards, which focus on the transfer of risks and rewards.

Companies in the pharmaceutical and life sciences industry might account for product sales to a distributor utilizing the sell-through model under current guidance if a reliable estimate of product returns cannot be made. Under the new guidance, revenue is recognized when control of the product transfers to the customer. This could result in a company that currently utilizes a sell-through model recognizing revenue upon shipment to the distributor under the new guidance. The amount of revenue recognized will be the amount that is probable (US GAAP) or highly probable (IFRS) of not resulting in a significant reversal of cumulative revenue in the future.

Similarly, some companies in the industry sell product with terms that are “Free on Board” (FOB) Shipping Point but, in practice, hold risk of loss in transit as the companies replace goods damaged or lost in transit. In those instances, companies recognize revenue when risks and rewards transfer (i.e., at destination). Under the revenue standards, companies will need to determine when they have transferred control of the product under arrangements with these terms, which may result in earlier revenue recognition than under current practice.

**Example 5-1 – Synthetic FOB destination**

**Facts:** A pharmaceutical drug manufacturer (“vendor”) sells drugs to its customers. The vendor’s standard sales contracts contain FOB shipping point terms, and it is clear that title legally transfers at the time the product is provided to the common carrier to be shipped to the customer. At the same time, the vendor has a history of replacing or crediting lost or damaged shipments. When a customer indicates that a product has been lost or damaged, the vendor provides the customer with a credit to their account or replaces the damaged product at no cost to the customer. Upon shipment, the vendor issues the invoice to the customer using customary payment terms. Over the last three years,
customer claims averaged less than 0.2% of total orders and 0.1% of total revenues. The vendor has reimbursed all claims for each of the last three years.

When should the vendor recognize revenue from the sale of the products?

**Analysis:** Companies should assess the indicators for determining when control transfers.

In this case, it would appear that most of the indicators point to the transfer of control having occurred at the point of shipment. The vendor would need to evaluate whether its past practice of replacing lost or damaged product represents a separate performance obligation or possibly a guarantee. However, the vendor may conclude that the promise to replace lost or damaged product is immaterial in the context of the contract and, as such, an assessment of this promise as a separate performance obligation is not required. Instead, the estimated costs to replace lost or damaged goods, developed using historical experience, would be accrued at the time revenue is recognized for the product shipment.

**Example 5-2 – Sale of product to a distributor with price protection clause**

**Facts:** Manufacturer sells product into its distribution channel. In its contracts with distributors, Manufacturer provides price protection by reimbursing its distribution partner for any difference between the price charged to the distributor and the lowest price offered to any customer during the following six months.

When should Manufacturer recognize revenue?

**Analysis:** Manufacturer should recognize revenue upon transfer of control of the product to the distributor. The price protection clause creates variable consideration. Manufacturer should estimate the transaction price using either the expected value approach or most likely amount, whichever is more predictive.

As previously discussed, the estimate of variable consideration is constrained to the amount that is probable (US GAAP) or highly probable (IFRS) of not reversing. Manufacturer will need to determine if there is a portion of the variable consideration (that is, a minimum amount) that would not result in a significant revenue reversal. Relevant experience with similar arrangements that allow Manufacturer to estimate the transaction price, taking into account the expected effect of the price protection provision, could result in earlier revenue recognition as compared to current practice.

**Contract manufacturing and other service arrangements**

Some companies in the pharmaceutical and life sciences industry serve other companies in the industry on a contract-by-contract basis to provide various services. Examples include:

- Contract manufacturing organizations (CMO’s) that perform services ranging from drug development to drug manufacturing
- Medical device companies that develop specialized equipment based on customer needs and specifications
- Biotechnology companies that perform research and development services
- Contract research organizations (CRO’s) that perform services to facilitate the clinical trial process

Accounting for these sorts of arrangements may change under the revenue standards as management must determine whether the performance obligation is satisfied at a point in time or over time. We do not expect a significant change in practice for many services; however, some products recognized at a point in time on final delivery today (e.g., highly customized goods) could be recognized over time under the new guidance. In order to make this determination, management will need to apply judgment to assess whether the asset has no alternative use and whether contract terms provide the right to payment for performance completed to date.

For performance obligations satisfied over time, companies will use a measure of progress that depicts its performance in transferring control of the promised good or service to the customer, which could be an output or an input method. The revenue standards require that companies apply a single method to measure progress for each performance obligation satisfied over time. This could be challenging, particularly when the individual goods or services included in a single performance obligation will be transferred over different periods of time or for contracts that include upfront payments.

To the extent a company uses an input method (for example, costs), it is important to include all relevant information that reflects the measure of progress in satisfying the performance obligation (that is, both internal and external costs). Time-based methods to measure progress may be appropriate in situations when a performance obligation is satisfied evenly over a period of time or a company has a stand-ready obligation to perform over a period of time. However, it is
not appropriate to default to straight-line attribution unless that depicts the pattern of transferring control to the customer.

Sometimes, companies are not able to reasonably determine the outcome of a performance obligation or its progress toward satisfaction of that performance obligation. In these instances, companies may recognize revenue over time as work is performed, but only to the extent of costs incurred (that is, with no profit recognized) as long as the company expects to at least recover its costs. This practice should be discontinued once management has better information and can estimate a reasonable measure of performance.

Example 5-3 – Contract manufacturing revenue recognition

Facts: Vendor is hired by Customer to manufacture a batch of 100,000 units of a drug with specific package labelling. The initial contract term is six months. Once bottled and labelled, there are significant practical limitations that preclude Vendor from redirecting the product to another customer. Vendor also has an enforceable right to payment for performance completed to date if the contract is cancelled for any reason other than a breach or non-performance.

Under current practice, Vendor recognizes revenue upon shipment of all 100,000 units to Customer.

When should Vendor recognize revenue under the revenue standards?

Analysis: Vendor should recognize revenue upon transfer of control of the product to the distributor. In this case, the drug to be manufactured by Vendor has no alternative use to Vendor (that is, the bottled and labelled product imposes a practical limitation that precludes Vendor from redirecting it to another customer). Also, Vendor has an enforceable right to demand payment if Customer cancels the contract. Therefore, Vendor should record revenue overtime as the units are manufactured.

Bill-and-hold arrangements

Pharmaceutical, biotechnology, and medical device companies may have bill-and-hold arrangements with their customers under which a company bills a customer for a product, but does not ship the product until a later date. For example, a company may hold inventory produced with a customer’s active pharmaceutical ingredient (API) for shipment to the customer in the future.

The revenue standards focus on when control of the goods transfers to the customer to determine when revenue is recognized. Depending on the terms of the contract, control may be transferred either when the product is delivered to the customer site or when the product is shipped. However, for some contracts, a customer may obtain control of a product even though that product remains in a company’s physical possession. In that case, the customer has the ability to direct the use of, and obtain the remaining benefits from, the product, even though it has decided not to take physical possession of the product.

For a customer to obtain control of a product in a bill-and-hold arrangement, the following criteria must be met: (1) the reason for the arrangement is substantive, (2) the product has been identified separately as belonging to the customer, (3) the product is ready for delivery in accordance with the terms of the arrangement, and (4) the company does not have the ability to use the product or sell the product to another customer. Companies will need to consider the facts and circumstances of their arrangements to determine whether control of the product has transferred to the customer prior to delivery. The requirement to have a fixed delivery schedule often precludes revenue recognition for bill-and-hold arrangements under current US GAAP; however, this requirement is not included in the revenue standards.

Government vaccine stockpile programs

Government vaccine stockpile programs require a company to have a certain amount of vaccine inventory on hand for use by a government at a later date. Prior to the adoption of ASC 606, the bill-and-hold criteria in US GAAP for revenue recognition are typically not met even though these arrangements were at the request of the government. For example, such arrangements generally do not include a fixed schedule for delivery and in some arrangements the vaccine stockpile inventory is not segregated from the company’s inventory. In many cases, companies rotate the vaccine stockpile to ensure it remains viable (that is, the product does not expire). The SEC has historically provided interpretive guidance for companies that participate in US Government vaccine stockpile programs, which under current guidance, permits them to recognize revenue at the time inventory is added to the stockpile, provided all other revenue recognition criteria have been met. For companies following US GAAP, the interpretive guidance applies only to US Government stockpiles and only to certain vaccines.
In August 2017, the SEC updated its interpretation on vaccine stockpile programs to conform to the guidance in ASC 606. The updated interpretation states that vaccine manufacturers should recognize revenue when vaccines are placed into US Government stockpile programs because control of the vaccines has transferred to the customer and the criteria in ASC 606 for recognizing revenue in a bill-and-hold arrangement are satisfied. The SEC has indicated that vaccine manufacturers should provide disclosures in accordance with ASC 606 when vaccines are placed into the stockpile. The interpretive guidance is only applicable to childhood disease vaccines, influenza vaccines, and other vaccines and countermeasures sold to the US Government for placement in the Strategic National Stockpile.

Companies that participate in government vaccine stockpile programs that do not meet the scope of the interpretive guidance will need to assess whether control of the product has transferred to the government prior to delivery under the revenue standards. The revenue standards do not require a fixed delivery schedule to recognize revenue, but the requirement for transfer of control may not be met if the stockpile inventory is not separately identified as belonging to the customer and is subject to rotation. Even if a company concludes that the bill-and-hold requirements of the revenue standards are met for certain of these arrangements, the company will need to assess the impact of obligations to replace or rotate expired and soon-to-be-expired vaccines for fresh product as these obligations could represent a return right.

In addition, all companies will need to consider their performance obligations under the arrangement. For example, companies need to assess if the storage of stockpile product, the maintenance of stockpile product, and the shipping of product are separate performance obligations.

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**Licenses of intellectual property**

Generally, a license granted by a company (the licensor) provides the customer (the licensee) with the right to use, but not own, the licensor’s IP. A common example in the pharmaceutical and life sciences industry is a company that “outsources” to a customer the IP it developed related to a drug that has not yet received regulatory approval. Often, under the terms of the license, the licensee can further develop the IP, and manufacture and/or sell the resulting commercialized product. The licensor typically receives an upfront fee, milestone payments for specific clinical or other development-based outcomes, and sales-based royalties as consideration for the license. Some arrangements also include ongoing involvement by the licensor, who might provide R&D and/or manufacturing services relating to the licensed IP.

Accounting for licenses could be challenging under the revenue standards. Determining whether a license is distinct from other goods and services in an arrangement is a key part of applying the model. Licenses coupled with other services, such as R&D, must be assessed to determine if the license is distinct (that is, both “capable of being distinct” and “distinct in the context of the contract,” as previously defined). If the license is not distinct, then the license is combined with other goods or services into a single performance obligation. Revenue is recognized as the licensor satisfies the combined performance obligation. Distinct licenses fall into one of two categories: (1) rights to use IP or (2) access rights to IP. The accounting for each category of license is described in the chart below.

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<th>New standards</th>
<th>Current US GAAP</th>
<th>Current IFRS</th>
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<tr>
<td><strong>Right to use IP</strong></td>
<td>Consideration is allocated to the license and revenue is recognized when earned, typically when the license is transferred if the license has standalone value.</td>
<td>Fees and royalties received for the use of a company’s assets (such as trademarks, patents, record masters and motion picture films) are normally recognized in accordance with the substance of the agreement. As a practical matter, this may be on a straight-line basis over the life of the agreement, for example, when a licensee has the right to use certain IP</td>
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<td>A license may provide a customer the right to use a company’s IP as it exists at the point in time the license is granted. For these licenses, revenue is recognized at a point in time when control transfers to the licensee and the license period begins.</td>
<td>If the license does not have standalone value, the license is combined with other deliverables, typically R&amp;D or manufacturing</td>
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<td>New standards</td>
<td>Current US GAAP</td>
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<tr>
<td><strong>Right to access IP</strong></td>
<td>A license may provide access to a company’s IP as it exists throughout the license period. Licenses that provide access are performance obligations satisfied over time and, therefore, revenue is recognized over time.</td>
<td>or technology for a specified period of time.</td>
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<td>Under IFRS 15, a license provides access to a company’s IP if all of the following criteria are met:</td>
<td>An assignment of rights for a fixed fee that permits the licensee to exploit those rights freely is, in substance, a sale if the licensor has no remaining obligations. Determining whether a license is a sale requires the use of judgment.</td>
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<td>- The licensor will undertake (either contractually or based on customary business practice) activities that significantly affect the IP to which the customer has rights.</td>
<td>When a license is sold with services or other deliverables, the vendor is required to exercise judgment to determine whether the different components of the arrangement should be accounted for separately.</td>
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<td>- The licensor’s activities do not otherwise transfer a good or service to the customer as they occur.</td>
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<td>- The rights granted by the license directly expose the customer to any effects (both positive and negative) of those activities on the IP.</td>
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<td>ASC 606 defines two categories of IP for purposes of assessing whether a license is a right to use or a right to access IP: (1) functional and (2) symbolic.</td>
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<td><strong>Functional IP (US GAAP)</strong></td>
<td>Functional IP includes drug formulas or compounds. A license to functional IP grants a right to use the entity’s IP as it exists at the point in time at which the license is granted unless both of the following criteria are met:</td>
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<td>- The functionality of the IP is expected to substantively change during the license period as a result of activities of the entity that do not transfer a promised good or service to the customer.</td>
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<td>- The customer is contractually or practically required to use the updated IP.</td>
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<td><strong>Symbolic IP (US GAAP)</strong></td>
<td>Symbolic IP is a right to access IP because of the entity’s obligation to support or maintain the IP over time.</td>
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<td>New standards</td>
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<td>If a licensing arrangement includes multiple goods or services (such as a license of IP and R&amp;D services), a company needs to consider whether the license is distinct. If not, it should be combined with other goods or services into a single performance obligation.(^2) In this case, revenue is recognized as the company satisfies the combined performed obligation.</td>
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<td>In order for the license to be considered distinct, the customer must be able to benefit from the IP on its own or together with other resources that are readily available to the customer, and the company’s promise to transfer the IP must be separately identifiable from other promises in the contract. The revenue standards provide indicators that assist in determining whether the IP is separately identifiable from other promises in the contract.</td>
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<td>Revenue cannot be recognized before the beginning of the period during which the customer can use and benefit from the licensed IP, notwithstanding when the license is transferred.</td>
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<td>Companies need to consider whether restrictions of time, geographical region, or use impact the identification of performance obligations in a licensing arrangement.</td>
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The revenue standards provide specific guidance for determining whether to recognize revenue from a license at a point in time or over time. Whether the license is a perpetual license or a term license does not necessarily impact the conclusion; rather, the terms of the contract, the rights granted to the licensee, and any activities the licensor undertakes that significantly impact the IP will impact that determination. Thus, the analysis under the revenue standards could result in different timing of revenue recognition as compared to today, depending on the company’s current accounting conclusions.

As discussed, a license to a drug formula or compound generally represents a right to use IP for which revenue is recognized at the point in time that control of the license transfers to the customer. This occurs when a customer is able to use and benefit from the license, but not before the beginning of the stated license period.

**Performance obligations**

Revenue might not be recognized immediately upon transfer of the right for more complex licensing arrangements that include other deliverables such as R&D services, manufacturing services, or arrangements in which the licensor undertakes activities that significantly impact the underlying IP. Guarantees that the patent to the IP is valid and

\(^2\)The revenue standards include an example specific to the pharmaceutical and life sciences industry to assist companies in evaluating whether a license is distinct.
actions to defend that patent from unauthorized use typically are not considered “activities” that significantly impact the underlying IP.

**Example 6-1 – Assessing distinct promises in a license and R&D services arrangement**

**Facts:** Biotech licenses a drug compound to Pharma. Biotech also provides R&D services as part of the arrangement. The contract requires Biotech to perform the R&D services but the services are not complex or specialized; that is, the services could be performed by Pharma or another qualified third party. The R&D services are not expected to significantly modify or customize the initial IP (the drug compound).

Is the license in this arrangement distinct?

**Analysis:** Whether a license is distinct from R&D services depends on the specific facts and circumstances. In this scenario, the license is distinct because the license is capable of being distinct and separately identifiable from other promises (that is, the R&D services) in the contract. Pharma can benefit from the license together with R&D services that it could perform itself or obtain from another vendor. The license is separately identifiable from other promises in the contract because the R&D services are not expected to significantly modify or customize the initial IP. The contractual requirement to use Biotech’s R&D services does not change the evaluation of whether the license and R&D services are distinct promises.

Conversely, in the case of very early stage IP (for example, within the drug discovery cycle) when the R&D services are expected to involve significant further development of the initial IP, a company might conclude that the license and R&D services are not distinct and, therefore, constitute a single performance obligation.

**Example 6-2 – Assessing distinct promises in a license arrangement with contractual restrictions**

**Facts:** Pharma licenses to Customer its patent rights to an approved drug compound for eight years beginning on January 1, 2017. Customer can immediately begin to utilize the IP to sell products in the United States. Beginning on January 1, 2019, Customer can utilize the IP to sell products in Europe. There are no other promises in the contract.

How many performance obligations are in the contract?

**Analysis:** Judgment is required to evaluate the impact of contractual restrictions of time, geography, or use in a licensing arrangement. In this case, Pharma would likely conclude that there are two distinct licenses (and, therefore, two performance obligations): a right to use the IP in the United States and a right to use the IP in Europe. This conclusion is based on the fact that there is an increase in rights for the same license over the license term (by expanding rights into Europe two years into the arrangement).

**Other considerations for evaluating distinct promises**

Companies will often perform manufacturing services in addition to the transfer of a license and performance of R&D services. Different conclusions may be reached on the identification of distinct promises based on the type of manufacturing performed. For example, if the manufacturing of active pharmaceutical ingredients is performed in support of the underlying R&D services, vendors might be more likely to conclude that the promises are not distinct since the company cannot fulfill its promise to perform R&D independent from its promise to manufacture API. Conversely, manufacturing of an approved product in support of commercialization efforts is more likely to result in a distinct promise if the manufacturing is not complex or specialized such that another party could perform the services.

Complex licensing arrangements will require careful consideration to determine whether the performance obligations should be accounted for separately. Companies will need to use judgment in evaluating the criteria and indicators in the revenue standards to ensure that combining or separating goods and services results in accounting that reflects the underlying economics of the transaction.

**Significant financing components in license arrangements**

License arrangements may contain payment terms that include upfront payments, installment payments, and/or minimum guaranteed royalties. Given the long-term nature of many license arrangements, companies in the pharmaceutical and life sciences industry will need to evaluate the timing of customer payments relative to the transfer of control of the licensed IP to determine if a significant financing component exists. For example, an arrangement may include a license to a drug formula or compound, the control of which generally transfers at the point in time the licensee can use or benefit from the license. A significant financing component may exist if the consideration is payable in installments (e.g., minimum guaranteed royalties) extending beyond one year.
**Milestone payments**

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<td>Milestone payments generally represent a form of variable consideration as the payments are likely to be contingent on the occurrence of future events. Milestone payments are estimated and included in the transaction price based on either the expected value (probability-weighted estimate) or most likely amount approach. The most likely amount is likely to be most predictive for milestone payments with a binary outcome (i.e., the company receives all or none of the milestone payment).</td>
<td>A substantive milestone is defined in ASC 605-28, Revenue Recognition – Milestone Method, and can include milestone payments received upon achievement of certain events, such as the submission of a new drug application to the regulator or approval of a drug by the regulator. A company that uses the milestone method recognizes revenue from substantive milestone payments in the period the milestone is achieved. Non-substantive milestone payments that are paid based on the passage of time or as a result of the licensee’s performance are allocated to the units of accounting within the arrangement and recognized as revenue when those deliverables are satisfied. A company that does not use the milestone method may use other revenue recognition models to recognize milestone payments (e.g., the contingency-adjusted performance model).</td>
<td>Milestone payments received for a license with no further performance obligations on the part of the licensor are recognized as income when they are receivable under the terms of the contract and their receipt is probable. The “milestone method” is often an appropriate method of accounting if it approximates the percentage of completion of the services under the arrangement. The milestone events must have substance, and they must represent achievement of specific defined goals. Management should consider the following factors to determine when milestone payments are recognized as revenue:</td>
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<td>Allocating milestone payments</td>
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<td>• The reasonableness of the milestone payments compared to the effort, time, and cost to achieve the milestones</td>
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<td>Allocating the variable amount entirely to the separate performance obligation or the distinct good or service reflects the amount of consideration to which the company expects to be entitled in exchange for satisfying that particular performance obligation when considering all of the performance obligations and payment terms in the contract.</td>
<td>• Whether a component of the milestone payments relates to other agreements or deliverables</td>
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<td>Recognizing milestone income</td>
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<td>• The existence of cancellation clauses requiring the repayment of milestone amounts received under the contract</td>
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<td>Variable consideration is only recognized as revenue when the related performance obligation is satisfied and the company determines</td>
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<td>• The risks associated with achievement of the milestones</td>
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<td>• Obligations under the contract that must be completed to receive payment or penalty clauses for failure to deliver</td>
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that it is probable (US GAAP) or highly probable (IFRS) that there will not be a significant reversal of cumulative revenue recognized in future periods. Companies will need to apply judgment to assess whether the amount of revenue recognized is subject to a significant reversal in the future.

Companies will need to evaluate, on an on-going basis, each milestone in a contract to determine whether including an estimate of variable consideration in the transaction price could result in a significant reversal of cumulative revenue recognized in the future.

**Example 6-3 – License of IP with development-based milestones**

**Facts:** Assume the same facts as Example 6-1. In addition to an upfront payment, the vendor is eligible to receive a milestone payment of $25 million upon the commencement of Phase III clinical trials and a milestone payment of $50 million upon regulatory approval. The vendor has extensive experience performing clinical trial services in similar R&D arrangements.

How may the vendor determine the transaction price at contract inception?

**Analysis:** Both contingent milestone payments are forms of variable consideration. Given the vendor’s extensive experience performing clinical trial services in similar R&D arrangements, the vendor may conclude that it is probable (US GAAP) or highly probable (IFRS) that a significant reversal in the amount of cumulative revenue recognized will not occur in the future when the uncertainty relating to this milestone is subsequently resolved. Therefore, the vendor may include the $25 million milestone for the commencement of Phase III clinical trials in the transaction price at contract inception, using the most likely amount method.

On the other hand, the vendor may not be able to assert at contract inception that it is probable (US GAAP) or highly probable (IFRS) a significant revenue reversal will not occur when the uncertainty associated with regulatory approval is subsequently resolved. This conclusion may be based on the current stage of development and the fact that regulatory approval (i.e., judgments and actions of third parties) cause the related variable consideration to be highly susceptible to factors outside of the company’s influence. Therefore, the vendor may exclude the $50 million milestone for regulatory approval in the transaction price at contract inception. However, as facts and circumstances change during the performance period, the vendor may be able to overcome the constraint and include the anticipated regulatory approval milestone in the transaction price once it becomes probable (US GAAP) or highly probable (IFRS) a significant revenue reversal will not occur in the future.

**Royalties**

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<tr>
<td>Sales- or usage-based royalties received in connection with the license of IP are subject to a specific exception in the revenue standards. For these licenses, the consideration is not included in the transaction price until the customer’s subsequent sales or usages occur, as long as this approach does not result in the acceleration of revenue ahead of the company’s performance. This exception is limited to licenses of IP with sales- or usage-based royalties</td>
<td>Royalties are recognized as they are earned and when collection is reasonably assured. Royalty revenue is generally recorded in the same period as the sales that generate the royalty payment.</td>
<td>Revenue from royalties accrues in accordance with the terms of the relevant agreement and is usually recognized on that basis unless it is more appropriate to recognize revenue on some other systematic basis.</td>
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New standards

and does not apply to other royalty arrangements.

In situations when royalties can relate to both a license of IP and other goods or services, the sales- or usage-based royalty exception only applies when the license of IP is the predominant item to which the royalty relates.

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In many cases, the accounting treatment of contingent royalty transactions will remain consistent with current practice under US GAAP and IFRS as royalty revenue is generally recognized as the underlying sales are made. However, the exception is limited to licenses of IP and does not apply to other transactions (e.g., sales) involving royalties.

Despite a number of examples in the implementation guidance, the terms “intellectual property,” “predominant,” and “royalty” are not defined under US GAAP or IFRS. As such, judgment will be required to determine whether an arrangement qualifies for the exception. Certain fixed payments might be in-substance variable sales- or usage-based royalties. For example, an arrangement might require a licensee to make a fixed payment that is subject to “claw back” if the licensee does not meet certain sales or usage targets. Conversely, some payments may not be described as royalties but are entirely dependent on the licensee achieving a sales target. There is no explicit guidance for these types of payments and therefore the accounting is dependent on an analysis of all of the facts and circumstances.

Distinguishing between a license of IP and a sale of IP will also be important under the revenue standards. If a company sells, rather than licenses, the IP, then the exception for excluding sales- and usage-based royalties from the transaction price is not applicable. Rather, a minimum amount of royalty revenue will be initially recognized if it is probable (US GAAP) or highly probable (IFRS) that a significant reversal of cumulative revenue recognized will not occur when the uncertainty is subsequently resolved. The initial estimate of royalty revenue is then updated each reporting period for changes in circumstances. Also, in the Basis for Conclusions of ASC 606, the FASB clarified that companies should not discern whether a license is an “in substance sale” of IP in deciding whether or not the royalties exception applies. The IASB did not make a similar statement, so companies reporting under IFRS may reach a different conclusion.

**Example 6-4 – License of IP with a sales-based milestone**

**Facts:** Biotech enters into an arrangement with Pharma in which Biotech agrees to provide Pharma a license to its IP, a drug compound. Biotech concludes that control of the license transfers at a point in time when the license period commences. In return, Pharma paid Biotech an upfront payment of $10 million and is required to pay Biotech an additional $20 million in the event Pharma’s annual sales of products associated with the IP exceed $250 million.

How should Biotech account for the contingent milestone consideration of $20 million?

**Analysis:** The $20 million sales-based milestone should generally be viewed as a sales-based royalty given it is based solely on Pharma’s subsequent sales.

Since the royalty exception applies to this scenario, instead of accounting for this milestone as variable consideration that would be estimated and included in the transaction price at contract inception (subject to the variable consideration constraint), the milestone would be recognized at the later of (1) when the subsequent sales or usage occurs or (2) full or partial satisfaction of the performance obligation to which some or all of the royalty has been allocated.

Therefore, as Biotech only had one performance obligation to transfer the license to Pharma, which was transferred at the beginning of the contract, Biotech should recognize the $20 million sales-based milestone when the sales threshold is reached.

**Minimum guarantees**

Arrangements in the pharmaceutical and life sciences industry may contain minimum royalty guarantees. In some cases, the minimum guarantee is negotiated due to uncertainty about the customer’s performance and its ability to successfully exploit the IP. In other cases, the minimum guarantee is established as a cash flow management tool to provide the licensor with predictable timing of some cash flows under the contract. Treatment of these arrangements...
may vary depending on whether the license is a “right to use” or a “right to access” the underlying IP. For a license that is a “right to use” IP, the minimum royalty guarantee is fixed consideration that should be recognized when a company transfers control of the license. The variable consideration (that is, the amount above the fixed minimum) should be recognized in accordance with the sales- and usage-based royalty exception. Conversely, for a license that is a “right to access” IP, a company may choose one of the following three models consistent with TRG Memo No. 58, Sales-Based or Usage-Based Royalty with Minimum Guarantee:

- Recognize revenue as the royalties occur if a company expects total royalties will exceed the minimum guarantee;
- Estimate the transaction price for the performance obligation (including fixed and variable consideration) and recognize revenue using an appropriate measure of progress, subject to the royalty constraint; or
- Recognize the minimum guarantee (fixed consideration) using an appropriate measure of progress and recognize royalties only when cumulative royalties exceed the minimum guarantee.

While we believe any of the three methods are reasonable, companies should select the method that best depicts the transfer of goods and services to customers. Companies should consider the nature of their arrangements and ensure that the measure of progress does not conflict with the core principles of the revenue standards, such as the royalty constraint or allocation principle. Companies should also appropriately disclose their judgments in this area, if material. Other methodologies may also be appropriate if they meet the core objective of the revenue standards.

**Example 6-5 – License of IP with a sales-based milestone and guaranteed minimums**

**Facts:** Biotech transfers to Pharma a license to a drug compound ready for commercialization. There are no other performance obligations in the contract. In addition to a $50 million upfront payment, Biotech is entitled to:

- A minimum guaranteed amount of $5 million for each year during the 10-year license term (for a total minimum guarantee of $50 million)
- An additional $20 million milestone each year in the event Pharma’s sales of products associated with the licensed IP exceed $250 million for that particular year. Biotech believes it is highly likely that these milestones will be earned.

What amount of revenue should be recognized upon transfer of the license?

**Analysis:** The minimum guaranteed milestones (or royalties) are not variable consideration. Rather, they represent fixed consideration that should be recognized when the license is transferred to Pharma. Assuming Biotech concludes that there is no significant financing component in the arrangement, it would recognize as revenue $100 million at the point in time the license is transferred, comprising the $50 million upfront payment and the total minimum guaranteed milestones of $50 million.

Conversely, if Biotech concludes that there is a significant financing component in the arrangement, it would reduce revenue to be recognized upon transfer of the license for the amount that represents future interest income. The amount of milestones in excess of the minimum guarantee (i.e., the annual $20 million potential milestone) will be recognized in accordance with the sales- and usage-based royalty guidance.

**Royalties in arrangements with two or more promises**

Additional complexity arises when a license of IP is bundled with other goods and services. The sales- and usage-based royalty guidance only applies to these arrangements if the license of IP is the sole or predominant item to which the royalty relates. A license of IP might be the predominant item to which the royalty relates, for example, when the customer would ascribe significantly more value to the license than to the other goods or services in the arrangement. Companies would apply the general variable consideration guidance to estimate the transaction price if the license of IP is not the predominant item. Judgment is required in making this determination. Management should not “split” the royalty and apply the exception to only a portion of the royalty stream.

**Example 6-6 – License of IP is predominant**

**Facts:** Pharma licenses its patent rights to an approved, mature drug compound to Customer for a license term of 10 years. Pharma also promises to provide training and transition services relating to the manufacturing of the drug for a period not to exceed three months. The manufacturing process is not unique or specialized, and the services are intended to help Customer maximize the efficiency of its manufacturing process. Pharma concludes that the license and
services are distinct. The only compensation for Pharma in this arrangement is a percentage of Customer’s sales of the product.

Does the sales- and usage-based royalty exception apply to this arrangement?

Analysis: Yes. The exception applies since the license of IP is predominant in the arrangement. This is because Customer would ascribe significantly more value to the license than to the services. Following the exception, Pharma would recognize revenue as the sales occur, assuming this approach does not accelerate revenue ahead of performance.

Collaborations arrangements

Pharmaceutical and biotechnology companies frequently enter into strategic collaborations and licensing arrangements. The revenue standards require companies to assess whether the counterparty to the arrangement is (1) a customer or (2) a collaborator or partner sharing in the risks and benefits of the arrangement. For example, as discussed in the Scope section, an arrangement in which two parties share equally in the co-development of a drug compound, and then share equally in future profits earned on the commercialized drug, may be outside of the scope of the revenue standards.

The following example illustrates the principles of the five-step approach for an arrangement with multiple performance obligations that is in the scope of the standard.

Example 6-7 – A collaboration arrangement with multiple performance obligations

Facts: Biotech enters into a collaboration arrangement with Pharma. Biotech grants an IP license to a drug compound to Pharma and will perform R&D on the compound for four years. The compound is currently in Phase III clinical trials and the nature of the work to complete these trials is not specialized; it can be performed by companies other than Biotech. Biotech receives an upfront payment of $40 million, per-hour payments for R&D services performed, and a milestone payment of $150 million upon regulatory approval. Biotech estimates the payments for R&D services will be $12 million based on its expected effort taking into consideration past experience with similar arrangements.

Biotech determines a standalone selling price of $45 million for the license and $15 million for R&D services based on its estimate of the amount of hours necessary to perform R&D services plus a profit margin of 25%.

Although Pharma may cancel the contract at any time during the performance period, a substantive termination penalty must be paid to Biotech upon termination.

How should Biotech account for the arrangement?

Analysis: The arrangement is in the scope of the revenue standards as Biotech and Pharma have a vendor-customer relationship. The license and R&D services provided by Biotech to Pharma are the outputs of Biotech’s ordinary activities. Biotech would likely determine that there are two performance obligations in the arrangement: (1) transfer of the license and (2) performance of R&D services. This is because Pharma can benefit from the license on its own or with other readily available resources (i.e., because the services could be performed by other companies). Also, given the current stage of development, the R&D services are not expected to significantly modify or customize the IP but, rather, the services performed during Phase III clinical trials are to validate the usage and efficacy of the compound.

The most predictive approach for estimating the $150 million contingent milestone would be the most likely amount method since the outcome is binary (that is, the drug compound either will or will not be approved by the regulator). However, given that regulatory approval is highly susceptible to factors outside Biotech’s influence (e.g., judgment or actions of the regulator), Biotech is not yet able to overcome the constraint on variable consideration (i.e., conclude that it is probable (US GAAP) or highly probable (IFRS) that there would not be a significant reversal of cumulative revenue in the future). Therefore, at contract inception, Biotech would not include any amount relating to the contingent milestone in the transaction price.

At contract inception, the total transaction price is $52 million, which includes the upfront payment ($40 million) and the payments for R&D services ($12 million).

The estimated transaction price at inception ($52 million) should be allocated to both performance obligations based on the relative standalone selling prices. The transaction price at inception would be allocated 75% to the license and 25% to R&D as follows ($ million):
**Performance obligation** | **Standalone selling price** | **Allocation %** | **Upfront payment** | **Payments for R&D** | **Total**
--- | --- | --- | --- | --- | ---
License | 45 | 75% | 30 | 9 | 39
R&D services | 15 | 25% | 10 | 3 | 13
**Total** | 60 | 100% | 40 | 12 | 52

**Transfer of the license**

Biotech transfers the license at the inception of the contract. The license provides Pharma with the right to use Biotech’s IP. Upon transfer of control of the license to Pharma, Biotech would recognize $39 million of revenue.

**R&D services**

Biotech would recognize the $13 million of revenue allocated to R&D services over the estimated service period based on a pattern that reflects the transfer of the services. The revenue recognized should reflect the level of service in each period. In this case, Biotech could use an input model that considers actual labor hours expended each period compared to the total labor hours expected to be expended during the entire performance period.

The transaction price should be re-assessed at each reporting date. Biotech would include $150 million from the milestone payment in the total estimated transaction price at the point in time it determines it is probable (US GAAP) or highly probable (IFRS) such amount is not subject to significant reversal in the future. At that time, Biotech should determine if it should allocate the milestone payment entirely to a specific performance obligation (that is, the license or the R&D services) or to both performance obligations. The revenue standards provide guidance to help companies with this judgment.

**Other considerations**

**Principal versus agent (gross versus net)**

Some arrangements involve two or more unrelated parties that contribute to providing a specified good or service to a customer. In these instances, management will need to determine whether the company has promised to provide the specified good or service itself (as a principal) or to arrange for those specified goods or services to be provided by another party (as an agent). The determination of whether a company is acting as a principal or as an agent in a revenue transaction continues to require significant judgment, and different conclusions can significantly impact the amount and timing of revenue recognition.

Management should first obtain an understanding of the relationships and contractual arrangements among the various parties. This includes identifying the specified good or service being provided to the end customer and determining whether the company controls that good or service before it is transferred to the end customer. It is not always clear whether the company obtains control of the specified good or service. The revenue standards provide indicators to help management make this assessment.

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<th>New standards</th>
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<tr>
<td>A company is the principal and should report revenue on a gross basis if it controls the specified good or service before it is transferred to the customer. When another party is involved in providing goods or services to a customer, a company that is a principal obtains control of any of the following:</td>
<td>Current US GAAP provides indicators to determine whether gross or net reporting is more appropriate. The indicators that support gross reporting are:</td>
<td>A company presents revenue gross if the gross economic benefit from the business activity results in an increase in the company’s equity. Alternatively, the company presents revenue net if the gross economic inflows include amounts collected on behalf of the principal.</td>
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<td>• A good or another asset from the other party that it then transfers to the customer.</td>
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<td>• A right to a service to be performed by the other party, which gives the company the ability to direct that party to</td>
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<td>• The company is the primary obligor in the arrangement</td>
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<td>• The company has general inventory risk</td>
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<td>• The company has latitude in establishing pricing</td>
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<td>• The company changes the product or performs part of the service</td>
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<td>• The company has discretion in supplier selection</td>
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**In depth**
## New standards

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<td>provide the service to the customer on the company’s behalf.</td>
<td>providing the goods or services</td>
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<td>• A good or service from the other party that it then combines with other goods or services in providing the specific good or service to the customer (for example, if a company provides a significant service of integrating the goods or services into the specified good or service for which the customer has contracted).</td>
<td>• Inventory risk</td>
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<tr>
<td>Conversely, a company is an agent and should report revenue on a net basis if its obligation is to arrange for another party to provide goods or services (i.e., the company does not control the specified good or service before it is transferred to the customer).</td>
<td>• Latitude in establishing price</td>
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<td>Indicators to assist companies in determining whether it controls the good or service before it is transferred to the customer are:</td>
<td>• Credit risk</td>
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<td>• The company is primarily responsible for fulfilling the promise.</td>
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<td>• The company has inventory risk.</td>
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<td>• The company has discretion in establishing the price.</td>
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<tr>
<td>Under the revenue standards, no single indicator is determinative or weighted more heavily than other indicators. However, some indicators may provide stronger evidence than others, depending on the circumstances.</td>
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<td>In a single contract, a company may act as a principal with respect to certain performance obligations and an agent with respect to others. Said differently, the principal versus agent assessment is at the performance obligation level, not at the contract level.</td>
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Although the indicators in the revenue standards are similar to those in the current guidance, the purpose of the indicators is different. A company is required to assess whether it controls the specified good or service, and the indicators are intended to support the control assessment. In contrast, the existing guidance is focused on assessing whether the company has the risks and rewards of a principal. Companies will therefore need to reassess their arrangements through the lens of the control principle.
The revenue standards also provide more guidance on the unit of account that should be used in the gross versus net assessment, which could result in changes to the assessment as compared to current guidance.

**Product warranties**

Many products are sold with implicit or explicit warranties indicating that the product sold to the customer meets a company’s quality standards and that the product is usable and not defective. Some companies also offer extended warranties, which provide for coverage beyond the standard warranty period.

The revenue standards draw a distinction between product warranties that the customer has the option to purchase separately (e.g., warranties that are negotiated or priced separately) and product warranties that the customer does not have the option to purchase separately. Judgment will need to be exercised when assessing a warranty not sold separately to determine if there is a service component to be accounted for as a separate performance obligation.

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<td>A company should account for a warranty that the customer has the option to purchase separately as a separate performance obligation.</td>
<td>Warranties that protect against latent defects are accounted for as a loss contingency and do not generally constitute a deliverable. A company records a liability for a warranty contingency and related expense when it is probable that a loss covered by the warranty has been incurred and the amount of the loss can be reasonably estimated. In determining whether the loss can be reasonably estimated, a company normally takes into account its own experience or other available information. Warranties that provide protection for defects that arise after the product is transferred are considered separate deliverables for which revenue is deferred and recognized over the expected life of the contract.</td>
<td>Products are often sold with a “standard warranty,” which protects the customer in the event that an item proves to have been defective at the time of sale (usually based on evidence coming to light within a standard period). This is not usually considered separable from the sale of goods. When the warranty is not a separate element, and represents an insignificant part of the sale transaction, the full consideration received is recognized as revenue on the sale and a provision is recognized for the expected future cost to be incurred relating to the warranty. If a company sells a product with an extended warranty, it is treated as a multiple-element arrangement and the revenue from the sale of the extended warranty is deferred and recognized over the warranty period. A provision is recognized for replacement only as defects arise through the warranty period. This differs from a standard warranty where provision is made at the time the goods are sold.</td>
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<td>A warranty that the customer does not have the option to purchase separately should be accounted for in accordance with existing guidance on product warranties so long as the warranty only provides assurance that the product complies with agreed-upon specifications.</td>
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<tr>
<td>A warranty, or a part of the warranty, that is not sold separately but provides the customer with a service in addition to the assurance that the product complies with agreed-upon specifications, creates a performance obligation for the promised service.</td>
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<td>A company that cannot reasonably separate the service component from a standard warranty should account for both together as a separate performance obligation.</td>
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Similar to existing US GAAP and IFRS, extended warranties give rise to a separate performance obligation under the revenue standards and, therefore, revenue should be recognized over the warranty period. Warranties that are separately priced under US GAAP may be impacted as the arrangement consideration will be allocated on a relative standalone selling price basis rather than at the contractual price. The amount of deferred revenue for extended warranties might differ under the revenue standards compared to current guidance as a result. Product warranties that are not sold separately and provide for defects that exist when a product is shipped will result in a cost accrual similar to current guidance.

**Example 6-8 – Medical device sale with optional warranty**

**Facts:** MedTech sells a medical device to Hospital with a twelve-month warranty that Hospital elected, but was not required to purchase.
How should MedTech account for the warranty?

**Analysis:** The revenue standards require MedTech to account for the 12-month optional warranty as a separate performance obligation because Hospital can purchase the warranty separately from the related goods. The fact that it is sold separately indicates that a service is being provided beyond ensuring that the medical device will function as intended.

MedTech allocates a portion of the transaction price to the warranty based on its relative standalone selling price. The amount of revenue allocated to the warranty could therefore differ from the stated price of the warranty in the contract. MedTech will need to assess the measure of progress for the promise to provide the warranty to determine when the revenue allocated to the warranty is recognized (that is, ratably over the warranty period or some other pattern).

If the twelve-month warranty was not optional, MedTech would assess whether the warranty only provides Hospital with assurance that the related product complies with agreed-upon specifications (that is, not a separate performance obligation) or provides a service that is a separate performance obligation.

**Contract costs**

Pharmaceutical and life sciences companies often pay commissions to internal sales agents and other employees. Commission plans can often be complex and involve a number of different employees. Some companies capitalize customer acquisition costs as an asset, while other companies expense the costs as incurred. The revenue standards require companies to capitalize incremental costs of obtaining a contract if the costs are expected to be recovered unless the costs qualify for the practical expedient that permits a company to expense incremental costs to obtain a contract when the expected amortization period is one year or less.

Companies may also incur costs, such as setup costs, to fulfill their obligations under a contract once it is obtained but before transferring goods or services to the customer. Management is first required to determine whether the accounting for these costs is addressed by other standards. If not, the costs to fulfill a contract are eligible for capitalization if all of the following criteria are met:

- The costs relate directly to a contract or a specifically-anticipated contract.
- The costs generate or enhance company resources that will be used in satisfying future performance obligations.
- The costs are expected to be recovered.

Companies should amortize any asset recognized from capitalizing costs to obtain or fulfill a contract (including capitalized sales commissions) on a systematic basis that is consistent with the transfer to the customer of the goods or services to which the asset relates. Determining the amortization period requires judgment and is similar to estimating the amortization or depreciation period for other assets (such as a customer relationship acquired in a business combination). Amortizing an asset over a longer period than the initial contract may be necessary if a company expects a customer to renew the contract and does not pay commissions on contract renewals that are commensurate with the commission paid on the initial contract. During the November 2016 TRG meeting, it was observed that the level of effort to obtain a contract or renewal should not be a factor in determining whether the commission paid on a contract renewal is commensurate with the initial commission. Rather, companies should assess whether the initial commission and renewal commission are reasonably proportional to the respective contract values.

Please refer to PwC’s Revenue guide for additional examples of capitalizing and amortizing contract costs.

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<tr>
<td>Companies will recognize as an asset the incremental costs of obtaining a contract with a customer if the company expects to recover those costs. All other contract acquisition costs that are incurred regardless of whether a contract was obtained (e.g., employee salaries and legal fees) are recognized as an expense. As a practical expedient, the revenue standards permit companies to</td>
<td>Companies may elect to capitalize certain costs to acquire a contract by analogizing to guidance on extended warranties or loan origination fees. Assets are typically amortized over the contract period. Companies can also elect to expense costs as incurred, unless specific guidance requires capitalization.</td>
<td>Given the lack of definitive guidance, some companies capitalize costs of acquiring customer contracts as intangible assets and amortize them over the customer contract period, while other companies expense the costs when incurred.</td>
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## New standards

### Expense incremental costs of obtaining a contract when incurred if the amortization period of the asset would be one year or less.

Contract costs recognized as an asset are amortized on a systematic basis consistent with the pattern of transfer of the goods or services to which the asset relates. In some cases, the asset might relate to goods or services to be provided in future anticipated contracts (for example, service to be provided to a customer in the future if the customer chooses to renew an existing contract).

An impairment loss is recognized if the carrying amount of an asset exceeds:

1. The amount of consideration to which a company expects to be entitled in exchange for the goods or services to which the asset relates; less
2. The remaining costs that relate directly to providing those goods or services.

Under the revenue standards, companies no longer have the option to capitalize or expense costs to obtain a contract. All incremental costs must be capitalized if the company expects to recover the costs, subject to the practical expedient. Incremental costs could include amounts paid not just to a single salesperson, but amounts paid to multiple employees (e.g., a salesperson, manager, and regional manager) if the payment would not have been incurred if the contract had not been obtained. Companies will have to apply judgment to identify all costs that are incremental and to determine the amortization period of the resulting asset.

Under IFRS, companies may reverse previous impairments when costs become recoverable; however, the reversal is limited to an amount that does not result in the carrying amount of the capitalized acquisition cost exceeding the depreciated historical cost.

Companies are not permitted to reverse impairments under US GAAP.

### Example 6-9 – Incremental costs to obtain a contract

**Facts:** A company’s vice president of sales receives a quarterly bonus, which is partially based on total new contracts with customers entered into during the year. The bonus is also based on other factors, including individual performance. The compensation committee has discretion to determine the final amount of the bonus payment and may decide not to pay any bonus.

Is the quarterly bonus considered an incremental cost to obtain a contract?

**Analysis:** No, the payment is based on factors other than obtaining new contracts; therefore, it would not be considered an incremental cost of obtaining a specific contract.

### Disclosures

The revenue standards include extensive disclosure requirements intended to enable users of financial statements to understand the amount, timing, and judgments related to revenue recognition and corresponding cash flows arising from contracts with customers.
The following are some of the more significant disclosure requirements, but the list is not all-inclusive.

The disclosures include:

- qualitative and quantitative information about contracts with customers;
- a reconciliation of contract balances;
- the significant judgments, and changes in judgments, made in applying the guidance to contracts with customers; and
- assets recognized from the costs to obtain or fulfill contracts with customers.

The disclosure requirements are more detailed than currently required under US GAAP or IFRS and focus significantly on the judgments made by management. For example, they include specific disclosures of the estimates used and judgments made in determining the amount and timing of revenue recognition. Pharmaceutical and life sciences companies could face challenges in estimating standalone selling price for certain deliverables (such as licenses), as well as determining the transaction price for variable consideration, and the judgments and methods used to make the estimates will have to be disclosed.

The revenue standards also require a company to disclose information about its remaining performance obligations, including the transaction price allocated to unsatisfied performance obligations and the expected timing of recognition. ASC 606 provides companies with an election to exclude quantitative disclosures for certain types of variable consideration, including sales- and usage-based royalties from licenses of IP and variable consideration allocated entirely to unsatisfied performance obligations. However, companies electing to exclude the quantitative disclosures are required to provide additional qualitative disclosures. Absent this election, companies will have to estimate the transaction price in these situations solely for purposes of the disclosure requirement.

Please refer to PwC’s Revenue guide for more information on disclosure requirements.
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At PwC, our purpose is to build trust in society and solve important problems. We’re a network of firms in 157 countries with more than 223,000 people who are committed to delivering quality in assurance, advisory and tax services.

We are dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. As a leader serving the industry with more than 4,500 industry-dedicated partners and staff worldwide, we have specialized advisory capabilities in research and development, supply chain management, sales and marketing, as well as in key operational areas, including finance, regulatory compliance, corporate development, information systems, and human resources management. Our commitment to the industry is broad-based and our clients include proprietary and generic drug manufacturers, wholesalers and distributors, specialty drug companies, medical device and diagnostics suppliers, biotechnology companies, pharmacy benefit managers, contract research organizations, and industry associations.

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