



Revenue for the life sciences industry

New standard.
New challenges.

US GAAP

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Revenue viewed through a new lens

Again and again, we are asked what's changed under the new standard: what do I need to tweak in my existing accounting policies for revenue? It's just not that simple.

The new standard introduces a core principle that requires companies to evaluate their transactions in a new way. It requires more judgment and estimation than today's accounting and provides new guidance to determine the units of account in a customer contract. The transfer of control of the goods or services to the customer drives the amount and pattern of revenue recognition; this is a change from the existing risks and rewards

model. As a result, there will be circumstances in which there will be a change in the amount and timing of revenue recognition. Even in circumstances where the effect of the new standard is not significant, a new analysis and controls are likely required.

Less has been said about disclosures, but the new standard requires extensive new disclosures.

This publication summarizes the most significant issues for life sciences industry – the issues that involve significant analysis and debate within the industry.

What's inside

- Contract term
- Contingent promises
- Identifying the arrangement with the customer
- Variable consideration
- Rights of return
- Licenses
- Sales- or usage-based royalties
- R&D services and licenses
- Collaborative arrangements
- Timing of revenue – over time
- Timing of revenue – point in time
- Sales to distributors
- Consignment activities
- Bill-and-hold arrangements
- Collectibility
- Applicable to all industries
 - Expanded disclosures
 - Transition
 - Effective dates
- Some basic reminders
- The impact on your organization
- KPMG Financial Reporting View
- Contacts

Contract term



An entity only accounts for the period of the contract in which there are enforceable rights and obligations.

The new standard is applied for the duration of a contract in which the parties to the contract have presently enforceable rights and obligations. The determination of the contract term is important because it could affect the number of performance obligations, measurement and allocation of the transaction price, timing of revenue recognition, contract modifications and the identification of material rights.

Often the contract term will be for the duration stated in the contract. However, the contract term can be shorter than the stated duration if both parties have the unilateral right to terminate the contract without paying a substantive penalty that compensates the other party. Similarly, if only

the customer has a right to terminate the contract without paying a substantive penalty, the contract term may be shorter than the stated term. In those situations, the contract term includes only the period that cannot be cancelled without substantive penalty.

The periods for which the customer can terminate the contract without paying a substantive penalty are treated as customer options and evaluated for the presence of a material right. That is because there is no substantive difference between a customer's decision to cancel future goods or services and a decision to renew or acquire the same additional goods and services.

Contingent promises



Some contracts include promises that are contingent on the occurrence or nonoccurrence of an event outside both parties' control.

Many contracts in the life sciences industry include promises to provide a good or service on the occurrence of a contingent event outside the control of both the entity and the customer. For example, a contract may require an entity to provide additional services or to manufacture a product when the customer obtains regulatory approval. We believe that in certain situations entities should consider contingent promises as similar to customer options and evaluate those promises for the presence of a material right. If a material right is not present, the contingent goods or services are accounted for separately – i.e. the initial contract term excludes contingent promises that do not convey a material right.

Indicators that a contingent promise that is outside the control of both the entity and the customer should be accounted for in the same way as a customer option (i.e. either a material right or separate contract) include:

- substantive uncertainty about the contingent event occurring;
- the occurrence of the contingent event requires incremental performance by the entity;
- the resolution of the contingent event requires the entity to transfer additional distinct goods or services; and/or
- the customer would be obligated to make an additional payment for the additional services.

Example – Service contract with contingent promises

ABC Corp. provides contract research services whereby it manages and conducts clinical trials on behalf of its customers. ABC does not license rights to IP or sell commercialized products.

ABC enters into a contract to provide services to Customer related to one of Customer's development-stage drug candidates. The contract obligates ABC to provide services for Phases 1, 2 and 3 of clinical trials in exchange for monthly fees and various milestone payments during each phase. Each stage of clinical trials requires regulatory approval; if approval is not received for a phase, ABC will not provide the subsequent phase(s) of service.

Because providing services in Phases 2 and 3 is contingent on an event outside the control of both ABC and Customer (approval), the Phase 2 and 3 services are contingent promises. ABC concludes that the contingent promises are akin to a customer option; this is because there is substantive uncertainty about the contingent event occurring and the contingent event requires additional distinct services and incremental payments.

As a result, the initial contract term only consists of Phase 1 services. Phases 2 and 3 are evaluated for the presence of a material right. If a material right is not present:

- all of the payments received in Phase 1 will be accounted for in that phase and not allocated to Phases 2 or 3; and
- none of the consideration associated with Phases 2 or 3 will be included in the transaction price for Phase 1.

Identifying the arrangement with the customer

Life sciences companies will need to evaluate arrangements with direct and indirect customers to account for the sale of a good or service.

Life sciences companies often have contracts directly with a customer, but with several downstream parties to whom the company may have promised to provide goods or services or to whom additional payments may be made. For example, a pharmaceutical company typically sells drugs directly to a distributor (i.e. the direct customer). That distributor will sell the drugs to a pharmacy or hospital that will sell the drug to a patient. Furthermore, the end customer may have an insurance company or government entity pay for the drug on its behalf. The pharmaceutical company could have arrangements with one or more of these parties in addition to the distributor.

The new standard requires that an entity consider whether promises to provide goods or services, or to make payments, to indirect customers should be accounted for as a part of the initial contract.

For example:

- A promise (explicit or implicit) to provide goods or services to an indirect customer could be a performance obligation in the contract.
- A payment to a customer or indirect customer should be evaluated to determine whether the payment is a reduction of the transaction price or a payment for a distinct good or service. If the payment is not for a distinct good or service, it will typically be considered variable consideration and reduce the transaction price in the sale to the distributor (see **Step 3: Determine the transaction price**).

A life sciences company will need to consider all of the arrangements along the distribution chain to correctly account for the contract with its direct customer.

Variable consideration



Rebates, discounts, chargebacks, price protection and outcomes-based pricing result in significant net price adjustments that need to be estimated.

It is common in the life sciences industry for transactions to involve variable consideration. Typical forms of variable consideration include rebates, discounts, rights of return, chargebacks and price protection – all of which are commonly referred to as ‘Gross to Net’ (GTN) revenue adjustments. Additionally, milestones and royalties are common forms of variable consideration in the industry.

Under legacy US GAAP, revenue was not recognized until a GTN deduction could be reasonably estimated, which many entities assessed based on experience. When entities had relevant experience with GTN adjustments, they made their best estimate and reduced the amount of revenue recognized. If a reasonable estimate could not be made because of a lack of experience, revenue was deferred. Other forms of variable consideration, such as milestones or royalties, were not recognized until the underlying contingency was resolved.

Under the new standard, variable consideration is estimated and included in the transaction price (subject to the constraint on variable consideration). An entity makes the estimate using the method below that will better predict the outcome.

- **Expected-value method.** The expected-value method is a probability-weighted estimate considering a range of potential outcomes. This method is typically more appropriate when there are a large number of potential outcomes or the entity has a large number of contracts with similar characteristics.
- **Most-likely-amount method.** This method is typically more appropriate if the contract only has two (or perhaps a few) possible outcomes.

We expect many life sciences companies to apply the expected-value method for typical GTN adjustments because of the large number of transactions and potential outcomes. In contrast, an entity might use the most-likely-amount method when estimating a milestone payment.

Entities will likely need to make additional judgments and refine or develop new processes to estimate and recognize these amounts under the new standard. For example, it may be difficult for some entities to determine the variable consideration to an indirect customer (e.g. insurer, government program) especially for a new rebate or discount program; this is because of the lack of visibility into the end user/payer that determines the rebate or refund payable.

The new standard provides an exception to estimating variable consideration for sales- or usage-based royalties in exchange for licenses of IP (see [Sales- or usage-based royalties](#)).

Volume-based rebates or discounts

Life sciences companies may provide incentives to their direct or indirect customers through volume rebates or discounts on future purchases. These incentives can take different forms. For example, some agreements provide a discount or rebate that applies to all purchases made under the agreement – i.e. the discount or rebate applies on a retrospective basis once a volume threshold is met. Under other agreements, the discounted purchase price may only apply to future purchases once a minimum volume threshold has been met.

Retrospective discount

If a discount applies retrospectively to all purchases under the contract once the threshold is achieved, the discount usually represents variable consideration under the new standard. In this case, the entity:

- estimates the volumes to be purchased and the resulting discount in determining the transaction price for each unit;
- updates that estimate throughout the term of the contract; and
- recognizes a reduction in revenue based on the estimated transaction price for each unit when control of the underlying product in the contract transfers to the customer.

A life sciences company includes variable consideration in the transaction price to the extent it is probable that a significant reversal of cumulative revenue will not occur when the uncertainty, in this instance cumulative volume, is resolved (the constraint on variable consideration).

The new standard may be different from legacy US GAAP in certain circumstances because of the constraint on variable consideration. For example, under legacy US GAAP, the maximum discount available was used if the entity was unable to make a reasonable estimate. The new standard does not default to the maximum discount, but requires entities to evaluate the probability and significance of a reversal of revenue to determine the estimated discount.

Future discount/material right

A life sciences company could grant its customer an option to acquire additional product at a discount. That option is a performance obligation if it provides a material right that the customer would not receive without entering into that contract. For example, a pricing structure that provides discounts on future purchases only after volume thresholds are met may convey a material right to the customer.

A material right exists if:

- the discount provides the customer with an option to purchase additional goods or services at a price that does not reflect their stand-alone selling prices; and
- those discounts are only earned as a result of the customer entering into the arrangement.

A material right may not exist if the discounts are provided to customers in the same class regardless of whether they had qualifying prior purchases. For example, assume Customer X receives a discount based on its volume purchases in the prior year, but the life sciences company provides that same discount to new customers of a similar size that were not required to make purchases in the prior year. The fact that the company does not require customers in a similar class to earn the discount indicates that the discounted pricing does not represent a material right.

If a material right exists, it is accounted for as a separate performance obligation; this results in revenue being allocated to the option and deferred until the option is exercised or expires. The amount of revenue deferred is based on the relative stand-alone selling price of the customer's option to acquire additional goods or services. If that price is not directly observable, the company will need to estimate it. This estimate reflects the discount that the customer would obtain when exercising the option, adjusted for:

- any discount the customer would receive without exercising the option; and
- the likelihood that the option will be exercised.

If a material right does not exist, there is no accounting for the future discount when recognizing revenue on the transactions completed before the volume threshold is met. Purchases after the threshold has been met are accounted for at the discounted price.

Milestone payments

A contingent milestone payment based on a non-sales metric such as a developmental-based milestone (e.g. obtaining regulatory approval) is considered variable consideration. In contrast, a milestone determined solely by reference to a sales or usage level (e.g. a milestone payment once a cumulative sales or usage threshold is reached) is subject to the royalty exception (see [Sales- or usage-based royalties](#)) rather than the variable consideration guidance.

A milestone payment that is variable consideration is estimated and included in the transaction price subject to the variable consideration constraint (see [Step 3: Determine the](#)

[transaction price](#)).

This is different from legacy US GAAP, which limited fees that could be recognized to only those that were fixed or determinable, and precluded the recognition of contingent revenue.

Applying the variable consideration constraint for developmental-based milestones could be challenging for life science companies because of the uncertainty of developmental activities. Some life sciences companies may conclude that developmental-based milestone payments are constrained because of a combination of the inherent uncertainty of the regulatory approval process for new drugs and the magnitude of the milestone payments in relation to cumulative revenue. However, even if a company concludes that the payment is initially constrained, as more information becomes available and the milestone payment nears, there may be circumstances in which the company may be able to conclude that the amount is no longer constrained. As a consequence, a milestone payment could be recognized earlier under the new standard if it is not constrained.

We believe that life sciences companies should evaluate the individual facts and circumstances of developmental-based milestones to assess whether the revenue should be constrained. The evaluation should include a robust analysis of the key judgments and considerations used for each milestone. Furthermore, companies should consistently apply the judgments about the constraint across all of their arrangements with similar facts and circumstances, but also identify and account for differences when they exist. It would not be appropriate to simply elect a broad policy of constraining or not constraining a particular type of milestone until it is achieved.

In many but not all cases, a life sciences company may conclude that milestones for final regulatory approval are constrained until it receives notice from the regulator. This is because of the magnitude of the milestone payments, the lack of predictive historical experience, and the fact that the outcome is based on the judgments of a third party (e.g. the FDA). For example, this may be the case when (not exhaustive):

- the candidate is based on new or novel medical science;
- the candidate is controversial; and/or
- the company (or partner) does not have extensive experience with the approval process or the past experience is not as relevant because of the unique circumstances of each drug candidate.

Notwithstanding the above, in other situations a life sciences company may conclude that a regulatory approval milestone is not constrained at some point before approval. While these milestones will typically be constrained early in the process when there is lack of clinical data to support approval, the company might be able to lift the constraint before approval as more relevant information about the likely or actual outcome of clinical trials or the application becomes available.

A life sciences company may be able to lift the constraint before approval when there is less risk in the approval process or historical experience is more relevant to the drug candidate. For example, when (not exhaustive):

- the approval for a generic drug is based on objective criteria (e.g. demonstrating biological equivalency) that the company can demonstrate before submitting the approval application; or
- a compound has previously been approved for other indications or for use with other technologies making the company's historical experience more relevant to the assessment.

In contrast to milestone payments triggered on final regulatory approval, other developmental-based milestone payments may not be as dependent on the judgment or actions of a third party (e.g. a regulatory agency). Examples of these developmental-based milestone payments include payments triggered on first dosing in a clinical trial or on moving from one phase to the next in the clinical trial process. For these types of milestones, a life sciences company may have relevant information that allows it to conclude that it is not probable that revenue attributable to a milestone will result in a significant reversal. Key considerations are the level of control the company has to achieve the milestone, the company's level of involvement and visibility into the process, and the company's assessments of the probability of success.

Outcomes-based pricing

In some situations, to sell a newly developed drug, a pharmaceutical company enters into an outcomes-based arrangement with the payer (e.g. government or insurer) or direct customer (e.g. government agency). Under these arrangements, the consideration to which the company is entitled could vary depending on whether there is measurable or observable improvement in patient health.

Under the new standard, even though the pharmaceutical company may only sell the drug to a distributor, the outcomes-based pricing arrangements with indirect customers (e.g. the payer) need to be evaluated as part of the sale to the distributor. Depending on the nature of the arrangement, the company might provide a rebate to the payer (an indirect customer) or the direct customer. In other scenarios, the company may provide additional dosages of the drug for no further cost. As a result, these arrangements could result in variable consideration or additional performance obligations.

Example – Outcomes-based pricing

Pharma sells its newly developed drug directly to distributors. In addition, Pharma has entered into an outcomes-based rebate arrangement with insurance companies whereby it provides a rebate if a patient who uses the drug (and is covered by the insurance company) does not show a measurable improvement in their condition.

Pharma concludes that its contract is with the distributor, but that the outcomes-based arrangement with the payer is consideration payable to a customer. Pharma does not receive a distinct good or service in exchange for the potential payment to the insurer and any rebate is a reduction of the transaction price and treated as variable consideration.

As a result, when Pharma sells its products to distributors, it estimates potential rebates using the expected-value or most-likely-amount method (whichever is more appropriate) and reduces the transaction price.

Medicare Part D Coverage Gap

Many pharmaceutical companies sell drugs subject to the Medicare Part D Coverage Gap – often referred to as the 'donut hole'. This government program requires pharmaceutical companies to pay a percentage of the cost of their branded drugs (through a payment to the insurer) when a patient falls within the coverage gap during a calendar year. The percentage was initially 50% and increases annually to a maximum of 75% by 2020 under current law. A patient covered by Medicare enters the coverage gap once the cost of prescription drugs purchased during the year (from all manufacturers) exceeds the amounts covered by Medicare. While in the coverage gap, patients pay only their portion of the drug cost and the pharmaceutical companies subsidize the remainder of the cost.

Under legacy US GAAP, there were multiple approaches used in practice to account for the coverage gap. Entities typically made an accounting policy election between a:

- **spreading approach**, whereby the company estimated the total coverage gap rebate for the year and recognized that amount on a constant percentage of sales throughout the year; and
- **point-of-sale approach**, whereby the company recognized a reduction of revenue at the time it sold the drug into the distribution channel that was expected to be sold to a patient in the coverage gap.

The new standard does not provide explicit guidance on this type of government program, and entities will need to consider their particular facts and circumstances to determine the right approach to account for the coverage gap.

Depending on the situation, we believe the following approaches may be appropriate.

- **Material right approach.** Under this approach, a company views coverage gap reimbursement requirements as giving rise to a material right. This is because the program in effect provides discounts on future purchases through the Medicare channel. The company allocates a portion of the transaction price to the material right, and recognizes that amount as revenue when patients use the coverage gap subsidies. Alternatively, companies may apply the alternative approach to allocating consideration to material rights if certain criteria are met (as defined in 606-10-55-45). Under the alternative approach, companies may estimate total expected consideration and allocate it proportionately with expected sales during the year. This approach could deliver a pattern of revenue recognition similar to the spreading approach used under legacy US GAAP.
- **Specific identification approach (i.e. variable consideration).** Under this approach, a company

views the coverage gap reimbursements as variable consideration attributable to individual sales of a product and not to overall annual sales. At the point of sale, the company estimates the amount of reimbursement that will be required for that particular sale, which reduces the revenue recognized. This approach could deliver a pattern of revenue recognition similar to the point-of-sale approach under legacy US GAAP.

While either approach may be reasonable in certain circumstances, we do not believe the material right approach is appropriate when 'donut hole' rebates are expected to be made predominantly in the early part of a year, which could be the case for a costly medication available from a single entity that must be taken periodically. A pattern of providing most of the rebates on early sales is not consistent with the notion that the customer has obtained a discounted option to buy goods in the future.

Rights of return



Some life sciences companies may experience a change in how they estimate returns.

Under legacy US GAAP, revenue was recognized on product sales with a right of return when certain conditions were met, including the ability to reasonably estimate future returns.

The new standard requires an entity to estimate returns and evaluate the constraint on variable consideration in determining the amount of revenue to recognize. This approach of adjusting revenue for the expected level of returns and recognition of a refund liability is broadly similar to legacy US GAAP, but some aspects of the new standard may result in changes from past practice.

— **Estimation methodology.** Under the new standard, an entity is required to estimate sales returns using the more predictive of the expected-value method (e.g. probability-weighted estimates) or the most-likely-amount method (see **Variable consideration**). The expected-value method will generally be more predictive for sales returns.

After estimating returns, an entity applies the constraint on variable consideration, which limits revenue recognition to an amount that is probable of not having a significant reversal in the future. The constraint guidance is intended to ensure that adjustments to previously constrained product or services revenue generally only are upward (i.e. increases to revenue). Because legacy US GAAP only required future returns to be reasonably estimable, entities often recorded upward or downward adjustments to revenue as a result of the right of return guidance.

— **New product launch.** Under legacy US GAAP, if a reasonable estimate could not be made, revenue recognition was deferred until the return period lapsed or a reasonable estimate could be made. This was often the case when a life sciences company launched a new product and did not have sufficient history or data to make a reasonable estimate. In that case, the company often deferred revenue until it either had prescription data or the return period on product expiration passed.

Under the new standard, the lack of historical information does not result in defaulting to zero revenue recognition. An entity will need to estimate the transaction price subject to the constraint. While revenue could conceivably be constrained to zero, it is likely that most entities will have some information to recognize consideration for an amount greater than zero. This means that entities that are unable to reasonably estimate returns may recognize some revenue earlier under the new standard.

— **Presentation.** Under the new standard, the return is presented gross as a refund liability and an asset for recovery. This is a change in practice for entities that presented reserves or allowances for returns on a net basis. However, because returned pharmaceutical products typically cannot be re-sold and must be destroyed, many pharmaceutical companies will not be able to recognize an asset for expected returns.

Licenses



A distinct license of IP is subject to the new licensing guidance. If a license is not distinct, an entity considers the nature of the promise in granting the license that is part of the combined performance obligation to determine the timing of recognition.

Life sciences companies often license rights to IP to other entities. For example, a biotech company may license rights to a drug compound in development to a pharmaceutical company. Other entities may out-license the rights to a commercialized product to another entity.

Under legacy US GAAP, there was diversity in how entities recognized revenue for licensing transactions. Some entities recognized revenue from a license at the point of delivery, while others recognized revenue over the license period.

Under the new standard, a licensor recognizes revenue from licensing transactions based on the nature of the license. Some licenses provide the customer the ability to control the IP at a point in time (right-to-use licenses), and some licenses provide access to the IP over the term of the license (right-to-access licenses).

The new standard provides guidance to determine the different types of licenses and divides intellectual property into two categories.

- **Functional IP** has significant stand-alone functionality – e.g. drug formula, patent, biologic compound, the ability to process a transaction, perform a function or task, or be played or aired. Functional IP derives a substantial portion of its utility (i.e. its ability to provide benefit or value) from its significant stand-alone functionality.
- **Symbolic IP** does not have significant stand-alone functionality, and therefore substantially all of the utility of symbolic IP is derived from its association with the licensor's past or ongoing activities. Symbolic IP includes brands, trade names such as a sports team name, logos and franchise rights.

A license of functional IP is typically considered a right-to-use license that is satisfied at a point in time. In contrast, a license of symbolic IP is satisfied over time.

The new standard includes examples of a biological compound, drug formulas, other technology and patents underlying highly functional items as functional IP. Therefore, most licensing transactions in the life sciences industry will involve functional IP that is satisfied at a point in time. As a result, if life science companies recognized licensing revenue over time under legacy US GAAP, they will recognize revenue earlier for licensing transactions that do not involve the sales- or usage-

based royalties under the new standard (see [Sales- or usage-based royalties](#)).

A distinct license of functional IP *that is a separate performance obligation* is recognized at the point in time that the customer obtains control of the license. However, if a license is not a separate performance obligation (e.g. the license is combined with R&D services), the entity will evaluate the nature of the combined performance obligation (including the nature of the license) to determine if the performance obligation is recognized over time or at a point in time.

Contractual restrictions

Some contractual provisions or restrictions are attributes of a license that define the customer's right to use or access the entity's IP and do not change the nature of the license conveyed to the customer or the accounting for that license. However, other contractual provisions require an entity to transfer control of additional licenses. An entity needs to distinguish between these types of restrictions.

A restriction on time, geography or use is generally a contractual provision that represents an attribute of a license. In contrast, when the restriction is substantively a promise to transfer additional rights at a later point in time, it represents an additional license.

For example, a contract that conveys initial rights to a customer with a restriction that results in additional rights at a future date conveys a promise to transfer control of an additional license. This is because:

- a license is the contractual right to use or access IP and not the IP itself; and
- a customer obtains control of a license only when it can use and benefit from the license, which occurs no earlier than the beginning of the time period for which it can use those rights.

As a consequence, a customer does not control a right when a restriction prevents the customer from being able to use and benefit from that right until a future point in time. This is the case even if the entity has transferred a copy of the IP. Therefore, for accounting purposes that type of restriction indicates the entity still has an obligation to transfer control of those rights to the customer in the future.

Example – Contractual restrictions are attributes of a license

On January 1, Year 1, Drug Manufacturer enters into a three-year contract with Customer granting Customer the exclusive right to a drug formula in the United States and Canada for the term of the contract. However, Customer can only use the formula to produce a drug that treats a specified illness. The rights to the drug formula in the United States and Canada both commence on January 1, Year 1.

The term of the license (three years), the geographical scope of the license (United States and Canada only) and the usage limitations (only producing drugs that treat a specified illness) define the scope of Customer's rights. None of these provisions require Drug Manufacturer to transfer additional rights to use or access IP after January 1, Year 1, which is when Customer can begin to use and benefit from the rights conveyed by the contract.

Drug Manufacturer concludes that the contract is for a single license.

Example – Contractual restrictions result in a promise to transfer an additional license

Assume the same facts as the previous Example, except that the rights to the drug formula in Canada do not transfer until January 1, Year 2 – i.e. there is a one year hold-back period for the Canadian rights. Drug Manufacturer provides the formula to Customer immediately, and Customer has the right to use the formula in the United States immediately.

Drug Manufacturer considers whether the contract grants Customer a single license, subject to a use restriction, or two licenses. It concludes that the provision in the contract preventing Customer from using the drug formula in Canada for the first year requires Drug Manufacturer to transfer additional rights on January 1, Year 2 that Customer does not control as of January 1, Year 1. This is because Customer cannot use and benefit from those rights in Canada before that date.

Therefore, Drug Manufacturer concludes that the contract includes two promised licenses.

License renewals

Under the new standard, the recognition of revenue from customer renewals of a license is subject to the same conditions as revenue recognition from the original license. Specifically, an entity cannot recognize revenue from the renewal of a license of IP before (1) it provides (or otherwise makes available) a copy of the IP to the customer and (2) the beginning of the period in which the customer may use and benefit from the right to access or use the IP.

As a result of this specific guidance, revenue for a renewal of a right-to-use license is not recognized until the beginning of the renewal period rather than when the parties agree to the renewal. In a renewal of a license to functional IP, this applies even when the customer has already been provided with the IP. This may result in a change in practice for entities that recognized the fees on renewal rather than the beginning of the renewal term.

Sales- or usage-based royalties



Sales- or usage-based royalties are accounted for differently under the new standard when IP is licensed and when it is sold.

Sales- or usage-based royalties in a licensing arrangement

Licensing arrangements often involve the customer paying the licensor a sales- or usage-based royalty.

The new standard contains an exception to the general guidance on variable consideration for sales- or usage-based royalties that are (1) promised solely in exchange for a license of IP, or (2) promised in exchange for a license of IP and other goods or services when the license is the *predominant* item to which the royalty relates. The new standard states that the license may be the predominant item "when the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates."

Under the royalty exception, the fees are recognized at the later of when the subsequent licensee sales or usage occurs, and the satisfaction or partial satisfaction of the performance obligation to which the royalty relates.

Typically, a sales- or usage-based royalty promised in exchange for a distinct license to a drug compound or other technology will be recognized when the subsequent sales or usage occurs. That is because control of the license to functional IP is satisfied at a point in time, which typically occurs before the licensee's subsequent sale or usage of the IP. However, in some circumstances where the entity may need to refund a portion of the royalty (e.g. a royalty that includes a retrospective rebate), the entity will need to estimate the refund amount subject to refund using the general variable consideration guidance.

Guaranteed royalties

Any guaranteed royalties (e.g. a fixed minimum amount) are accounted for as fixed consideration and will be recognized at the point in time that the customer obtains control of the license rather than when the entity has the right to invoice the royalty. When the guaranteed royalties are received a number of years after the license of functional IP is transferred, entities need to consider whether a significant financing component is present.

Example – Minimum royalties

Pharma licenses rights to a drug compound to Customer and will receive a 10% royalty each time Customer sells the related drug. The contract also guarantees that Customer will pay a minimum of \$10 million if the sales-based royalties do not exceed \$10 million over the first 10 years.

Pharma recognizes the \$10 million guaranteed payment when control of the license transfers because the amount is not variable and therefore not subject to the royalty exception. Any amounts earned in excess of \$10 million are subject to the royalty exception, and will be recognized when the subsequent sales occur. Pharma also considers whether the \$10 million guaranteed payment terms create a significant financing component.

License vs. sale of a drug compound

The royalty exception applies to licenses of IP, but it does not apply to sales of IP. As a consequence, the form of the arrangement dictates whether the royalty exception applies. It applies even if the license could be seen as an in-substance sale of IP – e.g. a license that transfers control to all of the worldwide rights on an exclusive basis in perpetuity for all possible IP applications. As a result, the legal form of the agreement dictates the accounting.

Under legacy US GAAP, revenue from royalties was recognized when the sale or usage occurred. Under the new standard, an entity that sells IP will need to estimate the expected royalties subject to the constraint on variable consideration because the royalty exception does not apply. This may result in revenue being recognized when control of the IP is transferred to the customer rather than when the royalty is earned. As a result, life sciences companies that sell rather than license IP may recognize revenue earlier than under legacy US GAAP.

IP license is predominant item for royalty

The royalty exception may also apply when a license is a part of a contract that includes other goods or services, such as R&D and/or manufacturing, if the license is considered the predominant item to which the royalty relates. This evaluation may require a high degree of judgment. When the license is the predominant item, the royalty exception applies to the entire royalty. A royalty would not be split into a portion that is subject to the royalty exception and a portion that is subject to the variable consideration guidance.

Royalty recognition on a lag no longer permissible

Under legacy US GAAP, some entities recognized sales- or usage-based royalties on a lag basis – i.e. in the period subsequent to that in which the sales or usage occurred – because they did not receive reporting about the royalties that the customer owed until the subsequent period.

Under the new standard, lag reporting is not permitted. If subsequent sales or usage of the entity's IP is not known, it is estimated for the period.

Optional purchases vs. usage-based royalty

A provision that permits a customer to obtain control of additional licenses is subject to the same customer option guidance as any other goods or services (see [Customer options](#)). Therefore, the entity needs to determine if the option conveys a material right to the customer that is a performance obligation or is a marketing offer that is accounted for as a separate contract. In contrast, a customer's usage of a license that it already controls may result in an additional usage-based fee, which is subject to the royalty exception.

In a life sciences arrangement with functional IP, an option to acquire additional licenses and a license with a usage-based royalty may result in a similar accounting outcome to past practice when no material right is present. This is because a usage-based royalty is recognized when the usage occurs and an option to acquire an additional license is accounted for separately when control of the license transfers. However, if the contract conveys a material right, consideration in the initial contract will be allocated to the option.

Because of the potential for different accounting, life sciences companies will need to carefully evaluate whether a contractual provision is an option to purchase additional licenses or is a usage-based royalty.

— A contract likely includes an option to acquire additional licenses if the contract provision (1) describes an option for the customer to acquire incremental rights or capabilities to make use of the license and (2) each exercise of that option is a separate purchasing decision by the customer

that would obligate the entity to transfer control of the incremental rights or capabilities to the customer.

- A contract likely includes a usage-based fee if the contract provision merely describes how the customer will compensate the entity for the use of the rights and capabilities that it already controls. For example, each time the customer uses a license that it already controls, it entitles the entity to additional compensation.

Example – Contract contains a usage-based royalty

On January 1, Year 1, Drug Manufacturer enters into a 10-year contract with Customer granting it the exclusive right to a drug formula in the United States for purposes of treating heart disease. The rights to the drug formula commence on January 1, Year 1. Customer pays Drug Manufacturer a fixed fee on commencement of the license and a royalty each time Customer sells a product using the drug formula.

Drug Manufacturer concludes that the contract does not include a customer option, and the royalty generated each time the drug formula is used is subject to the royalties exception. This is because Customer is using the rights it controlled on commencement of the license.

Example – Contract contains an option to acquire additional licenses

Assume the same facts as the previous Example, except that the contract also provides Customer with the option to license the rights to use the drug formula to treat diabetes for an additional fixed fee due after exercise of the option. Customer will also pay a royalty each time the drug formula is used in a product to treat diabetes.

Drug Manufacturer concludes that the contract includes a license to use the drug formula for purposes of treating heart disease and an option to purchase incremental rights to use the formula to treat diabetes. This is because Customer has a purchasing decision whereby it will acquire additional rights that it does not control on commencement of the initial license (i.e. rights to use the formula to treat diabetes).

As a consequence, Drug Manufacturer evaluates whether the option conveys a material right to Customer. The fixed fee due on exercising the option is not considered a usage-based royalty.

R&D services and licenses



Evaluating whether an R&D service and license are one or two units of account is different under the new standard.

In the life sciences industry, it is common for an entity to license development-stage IP and provide R&D services. For example, a biotech company often licenses rights to a drug compound to a pharmaceutical company and also agrees to provide R&D services with the goal of developing a commercialized product.

Under legacy US GAAP, to determine whether a license to a drug compound and R&D services were two separate units of account, a biotech company evaluated whether a drug license had stand-alone value apart from R&D services. The analysis often required an evaluation of any contractual limitations on the license – e.g. limitations on sub-licensing) and whether the services were highly specialized or proprietary.

Under the new standard, performance obligations are the units of account (see [Step 2: Identify the performance obligations](#)). To determine whether a drug compound license and R&D services are separate performance obligations, an entity determines whether those obligations are distinct from each other by evaluating whether they are both (1) capable of being distinct and (2) distinct in the context of the contract – i.e. separately identifiable. Many licenses require the licensee to use the licensor for R&D services. Such a contractual requirement would not prohibit the license from being distinct.

Capable of being distinct

A license is generally capable of being distinct if:

- the customer can use, consume or sublicense the rights on their own; or
- the R&D services are a readily available resource that is sold separately by the entity or others.

In contrast, if the R&D services are proprietary and not considered a readily available resource, the license is only distinct if the customer can benefit from the license without the services.

R&D services are generally capable of being distinct if:

- the entity sells the services on their own – i.e. without a related license. This indicates that customers can benefit from the services on their own and they are therefore capable of being distinct; or
- the customer can benefit from the services together with the license that has already been transferred to the

customer. Readily available resources include goods or services that have already been transferred. If the license is transferred at the beginning of the contract, the services will typically be capable of being distinct.

Distinct in the context of the contract

In making this assessment, an entity applies judgment to specific facts to determine whether a license and service are separately identifiable. This evaluation includes a consideration of whether the drug compound and services have a transformative effect on each other such that they are inputs into a combined output. In making this determination, the key analysis is typically whether the R&D services significantly modify or customize the drug compound so that the IP is significantly different at the end of the arrangement as a result of the services. This may be more frequent in early stages of development when the formula is being developed or when the services are developing an existing technology for a significantly different use.

In some cases, an entity may provide a significant integration service if the services integrate the licensed IP with the customer's IP to create a new combined functionality that neither the drug compound nor the customer's IP could provide on its own (i.e. create a combined output). However, this would not be the case when the two items are only additive such that each item provides the same functionality as it would on its own.

Finally, there may be circumstances in which R&D services are so integral to the customer's ability to derive benefit from the license that the license and services are effectively inputs to a single promise to the customer. This may be the case when the service involves proprietary knowledge of the entity in order for the customer to obtain the specified functionality from that license (e.g. an early stage compound or deriving new uses for the IP). However, in general, when other parties (including the customer) are capable of performing the services, it would be inappropriate to conclude that the promises are integral to the customer's ability to derive benefit from the license.

Though there may be judgment involved in assessing whether promises are distinct, once that conclusion is reached entities cannot choose to combine the license and R&D services into a single performance obligation.

Example – License to drug compound and related services: separate performance obligations

Biotech owns the IP to Drug Compound, which is currently in clinical trials. Biotech enters into an agreement with Customer whereby Biotech grants to Customer a license to Drug Compound. Biotech also agrees to continue performing R&D services with a goal of obtaining FDA approval for Drug Compound, which is needed to be able to bring the drug to market. The R&D services are designed around testing and validating the efficacy of the related compound and do not change the nature of the compound.

The license provides Customer with a right to use Biotech's IP and the performance of R&D services, which are the outputs of Biotech's ordinary activities. Although contractually the R&D services will be performed by Biotech, these services could be performed by Customer or any other third party qualified to continue these efforts. These services are sold separately by other vendors.

Biotech determines that the license as transferred and services are capable of being distinct. Customer can benefit from the license either alone or together with the services, which are a readily available resource because they are sold separately by other vendors. The services are capable of being distinct because Customer can benefit from the services together with the license that is transferred at the beginning of the contract.

Biotech next determines that the license and services are distinct in the context of the contract because the services do not change the underlying IP such that the license and services have a transformative effect on each other. That is, the services do not significantly modify or customize the IP. Furthermore, Biotech does not provide a significant service of integrating both the services and license into a combined output, and it could fulfill each promise independently. For example, Biotech could transfer the license and then transfer the services, which is further supported by other vendors providing the services on a stand-alone basis.

Example – License to drug compound and related services: combined performance obligation

Assume the same facts as the previous Example, except that Biotech is licensing rights to Drug Compound for three years to Customer, and enters into an agreement to provide R&D services with the goal of significantly modifying the biological compound so that Customer can integrate the compound with its new technology. In this example, without those services Drug Compound could not be used by Customer for its intended use, and other entities (including Customer) do not have the proprietary knowledge to perform the services. Biotech has licensed Drug Compound to other entities for different uses.

Biotech concludes that the license and services are not distinct based on the following.

- The license and service are capable of being distinct because the IP has been licensed separately to other parties and Customer could benefit from the services together with the license.
- However, the nature of the promise is to provide Customer with a significantly different compound with different functionality and therefore the license and services are not distinct within the context of the contract. The service is significantly modifying Drug Compound such that it has a transformative effect on the IP, and therefore the license and services are inputs into that combined output.

As a result, the license and services are combined into a single performance obligation.

Collaborative arrangements

Whether a collaborative arrangement is in the scope of the new revenue standard depends on whether the counterparty is a customer.

Many life sciences companies enter into collaboration agreements for the joint development and commercialization of IP such as a drug candidate. The relevant standard (Topic 808) defines collaborative arrangements and provides some guidance on presentation, classification and disclosures. However, it does not provide guidance on the recognition and measurement of payments between collaboration partners. Instead, it refers entities to other authoritative literature or, if there is no appropriate analogy, suggests that they apply a reasonable, rational and consistently applied accounting policy.

Under legacy US GAAP, there was diversity regarding how entities recognized, measured and presented payments received from collaboration partners. When the payments related to activities that are a part of the entity's ongoing major or central operations, the entity often applied revenue guidance. For example, a biotech company providing a license and R&D services to a pharmaceutical company typically applied the legacy standard (Topic 605) to those transactions.

When the activities are not a part of the entity's ongoing major or central operations, the entity often analogized to revenue guidance to recognize and measure payments received from the collaboration partner. In other scenarios, entities applied a cost-reimbursement approach for R&D services. For example, a pharmaceutical company in a collaborative arrangement with another pharmaceutical company may have concluded that licensing and providing R&D services are not a part of its ongoing major or central operations; therefore, it did not present the payments from collaboration partners as revenue.

The new standard does not change the guidance for collaboration arrangements and excludes from its scope contracts with a collaborator or a partner that are not customers, but rather share in the risks and rewards of participating in an activity or process. However, some or all of a collaborative arrangement is in the scope of the new revenue standard if the counterparty meets the definition of a customer. In that case, the entity applies the guidance in the new standard to separate and initially measure the part of the arrangement in its scope.

While the new standard does not address the recognition and measurement of collaborative arrangements when the counterparty is not a customer, if an entity is currently applying revenue guidance, either directly or by analogy, it would be inappropriate to continue to apply the superseded guidance on adoption of the new standard. As a result, entities that analogize to the existing revenue guidance will need to determine a new accounting policy, and we believe the new standard will generally provide an acceptable analogy.

Additionally, if the collaborating party is not deemed to be a customer, we expect some entities will continue to reflect certain payments received as cost reimbursements rather than revenue.

The FASB currently has a project to make targeted improvements to the guidance in Topic 808 to clarify when transactions between participants in a collaboration arrangement are within the scope of the new standard. An entity should proceed with its implementation and adoption efforts by making its best judgments about the appropriate guidance to follow while also following the FASB developments on this project.

Example – Collaboration partner is the customer for one party but not the other

Biotech has an arrangement with Pharma to research, develop and commercialize a drug candidate. Biotech is responsible for R&D activities, while Pharma is responsible for commercializing the drug candidate. Both Biotech and Pharma agree to participate equally in the results of the R&D and commercialization activities.

Because the parties are active participants and share in the risks and rewards of the drug candidate, this is a collaborative arrangement. However, Biotech also evaluates whether Pharma is a customer.

Biotech concludes that providing a license and R&D services are outputs of its ordinary activities and that Pharma is a customer. As a result, Biotech accounts for the contract under the new standard.

Pharma concludes that Biotech is not a customer because its ordinary activities are selling commercialized products. Therefore, the activities performed by Pharma in the collaboration are not an output of its ordinary activities and are not in the scope of the new standard. Instead, Pharma considers whether there is other authoritative literature or an appropriate analogy to account for the transaction. If not, it will apply a reasonable, rational and consistently applied accounting policy.

Example – Topic 606 applied by analogy

Pharma A has an arrangement with Pharma B to research, develop and commercialize a drug candidate. Pharma A and Pharma B will equally share product development expenses as well as product profits (sales less product-related costs). Pharma B also pays an up-front fee to Pharma A.

Pharma A transfers a license to the drug candidate to Pharma B and performs substantially all of the development activities. Pharma A will be responsible for commercialization activities in the United States, and Pharma B will be responsible for commercialization activities in Europe.

Pharma A concludes that providing a license and R&D services are not outputs of its ordinary activities because its ordinary activities are selling commercialized products and therefore Pharma B is not a customer. As a result, Pharma A concludes that the license and R&D services are not in the scope of the new standard.

Pharma A evaluates whether there is authoritative literature that applies either directly or by analogy and concludes that the new standard is an appropriate analogy to apply to the licensing and R&D services. As a result, Pharma A applies the recognition and measurement principles of the new standard, but does not present the amounts received for licensing and R&D services as revenue from customers. Pharma A would consider other applicable guidance to determine the presentation of the income 'below the line' as other income or as an offset to costs incurred.

Upon commercialization, Pharma A would also need to consider whether payments related to other portions of the collaborative arrangement are in the scope of the new standard (e.g. payments received after commercialization) and whether they should be presented as revenue or elsewhere in the income statement.

Timing of revenue - over time



Some life sciences companies that have historically recognized revenue at a point in time may be required to change to an over-time recognition model.

Under the new standard, entities need to evaluate each performance obligation to determine if the performance obligation is satisfied over time (see [Step 5: Recognize revenue](#)). If none of the over-time criteria are met, the entity recognizes revenue at a point in time.

R&D services

Under legacy US GAAP, entities that provided R&D services typically recognized revenue over time on a proportional performance basis. Similar to legacy US GAAP, entities providing R&D services will typically meet one of the criteria to recognize revenue over time under the new standard.

Under legacy US GAAP, entities might have applied an input or output method to recognize revenue for services. Under the new standard, an entity could also use an output method or an input method (e.g. cost-to-cost, labor hours incurred). However, the selection of a measure of progress is not a free choice and an entity needs to select a measure of progress that provides a faithful depiction of the transfer of services.

In many contracts, a single performance obligation may consist of promises or activities that are not distinct or have multiple payment streams associated with the services (e.g. up-front fees, milestone payments). Under the new standard, an entity must apply a single measure of progress for the performance obligation. For example, it would not be appropriate to apply a time-elapsed measure of progress to a significant up-front payment and an output measure based on the entity's right to bill (i.e. the as-invoiced practical expedient) to payments based on time and materials. As a consequence, an entity will need to apply significant judgment to determine a single measure of progress that depicts the entity's progress toward satisfying the single performance obligation.

Contract manufacturing

Life sciences companies may enter into contract manufacturing agreements. Under legacy US GAAP, these companies generally recognized revenue from contracts to manufacture drugs or devices at a point in time – when the manufactured goods were shipped or delivered to the customer – unless the bill-and-hold criteria were met.

Under the new standard, an entity that manufactures products designed to a customer's unique specifications may be required to recognize revenue as manufacturing occurs if the products have no alternative use to the manufacturer and the manufacturer has an enforceable right to payment for performance completed to date throughout the contract.

When evaluating whether the products have an alternative use, the manufacturer considers the end product that will ultimately be transferred to the customer. An enforceable right to payment exists if the manufacturer is entitled to payment of costs plus a reasonable margin on the work performed to date if the customer were to terminate the contract early for reasons other than the manufacturer's failure to perform as promised.

This analysis is performed on an individual contract basis for each performance obligation within a contract. Similar goods or services could have different patterns of recognition depending on the rights and obligations in each contract. Life sciences companies that manufacture products to customer specifications will need internal controls, policies and procedures to identify contract terms (e.g. a right to payment on termination) that would result in over-time versus point-in-time revenue recognition. Furthermore, these arrangements often have other elements to consider, such as pre-production activities, leases or other promised goods or services that need to be evaluated under the appropriate guidance.

Timing of revenue - point in time



Certain types of product sales will experience a change in the timing of revenue recognition based on when control transfers to the customer.

Under the new standard, if a performance obligation is not satisfied over time, then a life sciences company recognizes revenue at the point in time that it transfers control of the good or service to the customer. Control refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, the good or service. For a discussion of the timing of recognition for licenses, see [Licenses](#).

Under legacy US GAAP, life sciences companies typically recognized revenue from the sale of products when they relinquished the risks and rewards of ownership. The timing of revenue recognition could change in some circumstances under the new standard, because the focus shifts from transfer of risks and rewards to the transfer of control of the goods.

Under the new standard, the notion of risks and rewards is only an indicator of control. Other indicators, such as legal title, physical possession, right to payment and customer acceptance, also need to be evaluated based on the facts and circumstances of each arrangement.

Life sciences companies may have arrangements in which the products are shipped to the customer FOB shipping point. Under legacy US GAAP, these terms may have been treated as FOB destination arrangements (revenue was deferred until goods were received by the customer) because the company assumed the risk of loss during transit and determined that the risks and rewards of the goods did not pass to the customer at the shipping point. This is often referred to as 'synthetic FOB destination'.

Because the transfer of the risks and rewards of the asset is only one of the indicators for determining when the customer obtains control of the drugs under the new standard, control of the products may transfer when the drugs are shipped in synthetic FOB destination arrangements. As a result, many entities with synthetic FOB terms will recognize revenue earlier under the new standard.

Shipping and handling services

The accounting for shipping and handling under the new standard depends on whether the activities are performed before or after the customer obtains control of the drugs.

- If the shipping and handling occur *before* the customer obtains control of the drugs, they are fulfillment activities.
- If the shipping and handling occur *after* a customer obtains control of the drugs, an entity makes a policy election (and discloses its election) to treat these costs as:
 - fulfillment activities, in which case the entity accrues the costs of these activities and recognizes revenue and costs at the point in time that control of the drugs transfers to the customer – thereby achieving matching of the expense and revenue; or
 - a performance obligation, in which case the entity allocates a portion of the transaction price to the shipping and handling. Revenue allocated to the drugs is recognized *when* control of the drugs transfers to the customer, and revenue for the shipping and handling performance obligation is satisfied. The related costs are generally expensed as incurred.

Sales to distributors



Pharmaceutical companies applying the sell-through method of accounting will likely experience an acceleration of revenue and cost recognition.

Many drugs are sold directly to distributors or other resellers of the product. Under legacy US GAAP, some entities recognized revenue on a sell-through basis – i.e. when the product was sold to the end customer. However, under the new standard sell-through accounting is not appropriate if control transfers when the products are delivered to the distributor.

Under legacy US GAAP, some entities applied sell-through accounting because they were unable to reasonably estimate returns, rebates or price concessions. Instead, they recognized revenue when they had evidence that the product was sold to an end customer, which was often evidenced by the drug being prescribed to a patient (i.e. sell-through accounting), rather than when they sold products to the distributor (i.e. sell-in accounting).

Under the new standard, entities will generally conclude that control transfers to the distributor on a sell-in basis unless the product is transferred on a consignment basis. This is because the transfer of risks and rewards is only one of several indicators of control and the distributor can generally direct the use of and obtain the benefits from the products on delivery.

When the entity transfers control of the products to the distributors, the entity will be required to estimate the amount of consideration to which it expects to be entitled. That amount includes an estimate of returns or other price concessions and is constrained to the amount that does not result in a risk of significant reversal of revenue. However, in most circumstances it is unlikely that the transaction price will be constrained to zero. This estimate is updated each reporting period until the uncertainty is resolved.

The timing of control transfer is also important because the entity derecognizes its inventory and records cost of goods sold at that point – even if the revenue is significantly constrained because of the risk of a significant revenue reversal. As a result, in certain circumstances an entity may be required to recognize costs before recognizing much of the expected revenue; this is because the revenue was significantly constrained by the risks that caused the amount not to be fixed or determinable under legacy US GAAP.

Consignment activities



Similar to legacy US GAAP, revenue from consignment arrangements is not recognized when products are delivered to the intermediary.

Life sciences companies may enter into consignment arrangements whereby a counterparty, typically a distributor, may warehouse inventory while the company maintains control until a future date or subsequent re-sale.

The new standard provides the following indicators that an arrangement is a consignment arrangement.

- The entity controls the product until a specified event occurs, such as the sale of the product to a customer of the distributor or pharmacy, or until a specified period expires.
- The entity is able to require the return of the product or transfer the product to a third party, such as another distributor.

- The distributor does not have an unconditional obligation to pay for the products, although it might be required to pay a deposit.

These types of arrangements do not allow the entity to recognize revenue on delivery of the products to the intermediary because it has not transferred control of the products to the intermediary. The assessment of control is different from the risk-and-rewards approach under legacy US GAAP. However, consideration of whether the significant risks and rewards of ownership have been transferred is an indicator of the transfer of control, and conclusions about when control has passed to the intermediate party or the end customer are generally expected to stay the same for consignment arrangements.

Bill-and-hold arrangements

An explicit customer request and a specified delivery schedule are no longer required to recognize revenue under a bill-and-hold arrangement.

Under legacy SEC guidance on bill-and-hold arrangements, revenue was not recognized until all bill-and-hold criteria were met. The new standard focuses on when control of the good transfers to the customer.

Under the new standard, in addition to evaluating the indicators that control transfers at a point in time (see [Step 5: Recognize revenue](#)) all of the following criteria must be met:

- the reason for the bill-and-hold arrangement is substantive;
- the product is identified as separately belonging to the customer;
- the product is ready for physical transfer to the customer; and
- the entity does not have the ability to use the product or direct it to another customer.

While the application of the bill-and-hold guidance is not expected to be significantly different from the former SEC guidance, the criteria for bill-and-hold arrangements under the new standard differs in two key respects.

The bill-and-hold arrangement is not required to be at the customer's explicit request. The new standard requires the reason for the bill-and-hold arrangement to be substantive. An understanding of the business reasons is important.

The entity did not need a specified delivery schedule to meet the bill-and-hold criteria. However, the lack of a planned or estimated delivery date could indicate that a contract did not exist because the enforceable rights and obligations between the parties are not clear (see [Step 1: Identify the contract](#)). If a delivery schedule did not exist, it may have been important that the entity received appropriate consideration to hold the goods indefinitely to conclude that the parties were committed to their obligations and that a contract existed.

Under the new standard, an obligation to warehouse the goods after control has transferred to the customer may be a separate performance obligation and revenue would be allocated and recognized as the warehousing service is provided.

Vaccine stockpiles

Pharmaceutical companies enter into contracts to supply vaccines to a government agency under a stockpile program. A stockpile program requires these companies to retain a

certain number of vaccine doses on hand and to rotate any vaccine dose in the stockpile if its expiration date is within a certain period. The bill-and-hold revenue recognition criteria under SEC guidance were generally not met. This is because entities are required to rotate the vaccine stockpile to ensure they do not expire – i.e. a specified delivery schedule does not exist and the vaccine stockpile may not be segregated from the entity's inventory. However, the SEC provided an exception to its own guidance for entities participating in US government vaccine stockpile programs, which permitted those entities to recognize revenue at the time inventory was added to the stockpile, provided all other revenue recognition criteria were met.

The SEC updated its guidance for the new standard and indicated that vaccine manufacturers should recognize revenue and provide disclosures required under the new standard when vaccines are placed into US Federal Governmental stockpile programs; this is because control of the vaccines will have been transferred to the customer (i.e. the US Federal Government). The following enumerated vaccines are subject to this SEC guidance:

- childhood disease vaccines;
- influenza vaccines; and
- other vaccines and countermeasures sold to the US Federal Government for placement in the Strategic National Stockpile.

This interpretive guidance does not apply to transactions other than those described above with the US Federal Government. When the vaccines are placed into the US Federal Government stockpile, entities need to evaluate whether storage, maintenance (i.e. stock rotation), and shipping and handling of vaccine stockpiles are separate performance obligations because control of the vaccine doses transfers to the customer before the entity provides these services.

Entities with similar transactions with customers other than the US Federal Government should evaluate their facts and circumstances under the bill-and-hold guidance. We understand that many arrangements outside the scope of the SEC's interpretive guidance will not meet the criteria to recognize revenue under that guidance because either the product is not separately identified as belonging to a particular customer or the entity has the ability to direct the product to another customer.

Collectibility



Entities need to evaluate a customer's ability and intent to pay the consideration to which it expects to be entitled to determine that a contract exists for accounting purposes.

Under legacy US GAAP, collectibility being reasonably assured was one of the criteria that must have been met to recognize revenue. The new standard requires collection to be 'probable' to conclude that a contract exists. In other words, the collectibility criterion is a gating question designed to prevent entities from applying the revenue model to problematic contracts instead of the recognition criteria (see [Step 1: Identify the contract](#)).

In making the collectibility assessment, a life sciences company considers the customer's ability and intent to pay the amount of consideration to which it expects to be entitled in exchange for the goods or services that will be transferred to the customer. The amount may not be the stated contract price because the assessment is made after estimating any variable consideration. The amount expected to be entitled to is determined before considering credit risk-associated inability to pay.

It could be challenging to determine whether collecting less than the original transaction price is variable consideration rather than an indication that the customer does not have ability and intent to pay. The following factors might indicate that an entity intends to accept payment of a lesser amount than the contract/invoice price as variable consideration rather than a collectibility issue.

- The goods or services promised to the customer are not expected to expose the entity to a significant economic loss if the customer pays a lesser amount.

- The entity has previously chosen not to enforce its rights to the contract price in similar contracts with the customer (or class of customer) under similar circumstances. This pattern of accepting less consideration than promised in similar contracts may provide evidence that the entity will provide a potential reduction in price that is akin to variable consideration.
- The entity has experience (or other evidence) about the customer or class of customer not fulfilling its obligations to pay the promised consideration in other contracts. An entity's willingness to enter into a new contract with the customer despite that history may suggest that it will accept a reduction in the price.

Life sciences companies often enter into contracts with foreign government entities that do not pay within the stated period of time. A history of slow paying does not on its own indicate that collection is not probable. However, entities will need to carefully evaluate the ability and intent of that foreign entity to pay, including considering the current political and economic environment. When the entity has experience to suggest that collection is probable but beyond 12 months from when the goods or services are transferred, it should also consider whether there is an implied significant financing component even if the stated payment terms are less than one year.

Applicable to all industries

Expanded disclosures

The new standard contains both qualitative and quantitative disclosure requirements for annual and interim periods. The objective of the disclosures is to provide sufficient information to enable users of the financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

Specifically, the new standard includes disclosure requirements for:

- disaggregation of revenue;
- contract balances, including changes during the period;
- performance obligations;
- significant judgments; and
- assets recognized to obtain or fulfill a contract, including changes during the period.

An entity should review these new disclosure requirements to evaluate whether data necessary to comply with the disclosure requirements are currently being captured and whether system modifications are needed to accumulate the data.

Internal controls necessary to ensure the completeness and accuracy of the new disclosures should be considered – especially if the required data was not previously collected, or was collected for purposes other than financial reporting.

Also, SEC guidance requires registrants to disclose the potential effects that recently issued accounting standards will have on their financial statements when adopted¹. The SEC expects the level and specificity of these transition disclosures to increase as registrants progress in their implementation plans. The SEC has also stated, when the effect is not known or reasonably estimated, that a registrant should describe its progress in implementing the new standard and the significant implementation matters that it still needs to address.

Transition

An entity can elect to adopt the new standard in a variety of ways, including retrospectively with or without optional practical expedients, or from the beginning of the year of initial application with no restatement of comparative periods (cumulative effect method).

Entities that elect the cumulative effect method are required to disclose the changes between the reported results of the new standard and those that would have been reported under legacy US GAAP in the period of adoption.

For transition purposes, the new standard introduces a new term – completed contract. A completed contract is a contract for which an entity has recognized all or substantially all of the revenue under legacy US GAAP as of the date of adoption of the new standard. The concept of a completed contract is used when applying:

- certain practical expedients available during transition under the retrospective method; and
- the cumulative effect method coupled with the election to initially apply the guidance only to those contracts that are not complete.

This will require careful analysis particularly where there is trailing revenue after delivery has occurred (e.g. revenue was not fixed or determinable, collectibility was not reasonably assured, royalty arrangements). In those circumstances, the contract would not be considered complete if substantially all of the revenue had not been recognized before adoption. Applying the standard to these types of contracts at transition may result in revenue being pulled into the opening retained earnings adjustment.

Entities should consider the potential complexities involved with calculating the opening retained earnings adjustment and the recast of comparative periods (if any) when planning their implementation. It may be prudent for entities to perform transition calculations before the adoption date to ensure all potential complexities are identified.

Effective dates

Type of entity	Annual reporting periods after
Public business entities and not-for-profit entities that are conduit bond obligors	December 15, 2017 including interim reporting periods within that reporting period. Early adoption permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.
All other US GAAP entities, including SEC registrants that are Emerging Growth Companies	December 15, 2018 and interim reporting periods within annual reporting periods beginning after December 15, 2019. Early adoption permitted for annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period or interim reporting periods within the annual period subsequent to the initial application.

1. Staff Accounting Bulletin Topic 11.M.

Some basic reminders

Scope

The guidance applies to all contracts with customers unless the customer contract is specifically within the scope of other guidance – e.g. Topic 944 (insurance), Topic 460 (guarantees).

The new standard applies to contracts to deliver goods or services to a customer. A 'customer' is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration.

The new standard will be applied to part of a contract when only some elements are in the scope of other guidance.



Step 1: Identify the contract

Contracts can be written, oral or implied by an entity's customary business practices, but must be enforceable by law. This may require legal analysis on a jurisdictional level to determine when a contract exists and the terms of that contract's enforceability.

A contract with a customer is in the scope of the new standard when the contract is legally enforceable and all of the following criteria are met:

- the contract has commercial substance;
- rights to goods or services can be identified;
- payment terms can be identified;
- the consideration the entity expects to be entitled to is probable of collection; and
- the contract is approved and the parties are committed to their obligations.

If the criteria are not met, any consideration received from the customer is generally recognized as a deposit (liability).



Step 2: Identify the performance obligations

Performance obligations do not have to be legally enforceable; they exist if the customer has a reasonable expectation that the good or service will be provided. A promise can be implied by customary business practices, policies or statements.

Performance obligations are the unit of account under the new standard and generally represent the distinct goods or services that are promised to the customer.

Promises to the customer are separated into performance obligations, and are accounted for separately if they are both (1) capable of being distinct and (2) distinct in the context of the contract.

An exception exists if the performance obligations represent a series of distinct goods or services that are substantially the same and that have the same pattern of transfer to the customer over time. A series is accounted for as a single performance obligation.



Step 3: Determine the transaction price

Estimating variable consideration will represent a significant departure from prior accounting for many entities.

When determining the transaction price, an entity uses the legally enforceable contract term. It does not take into consideration the possibility of a contract being cancelled, renewed or modified.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer, excluding amounts collected on behalf of third parties – e.g. some sales taxes. This consideration can include fixed and variable amounts, and is determined at inception of the contract and updated each reporting period for any changes in circumstances.

The transaction price determination also considers:

- **Variable consideration**, which is estimated at contract inception and is updated at each reporting date for any changes in circumstances. The amount of estimated variable consideration included in the transaction price is constrained to the amount for which it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved.
- **Noncash consideration** received from a customer is measured at fair value at contract inception.
- **Consideration payable to a customer** represents a reduction of the transaction price unless it is a payment for distinct goods or services it receives from the customer.
- **Significant financing components** may exist in a contract when payment is received significantly before or after the transfer of goods or services. This could result in an adjustment to the transaction price to impute interest income/expense.



Step 4: Allocate the transaction price

A contractually stated price or list price is not presumed to be the stand-alone selling price of that good or service.

The transaction price is allocated at contract inception to each performance obligation to depict the amount of consideration to which an entity expects to be entitled in exchange for transferring the promised goods or services to the customer.

An entity generally allocates the transaction price to each performance obligation in proportion to its stand-alone selling price. However, when specified criteria are met, a discount or variable consideration is allocated to one or more, but not all, performance obligations.

The stand-alone selling price is the price at which an entity would sell a promised good or service separately to a customer. Observable stand-alone prices are used when they are available. If not available, an entity is required to estimate the price using other techniques – even if the entity never sells the performance obligation separately.



Step 5: Recognize revenue

An entity must first determine whether a performance obligation meets the criteria to recognize revenue over time.

If none of the over-time criteria are met, revenue for the performance obligation is recognized at the point in time that the customer obtains control of the goods or services.

Control is the ability to direct the use of, and obtain substantially all of the remaining benefits from the goods or services – or prevent others from doing so.

An entity recognizes revenue when it satisfies its obligation by transferring control of the good or service to the customer.

A performance obligation is satisfied **over time** if one of the following criteria are met:

- the customer simultaneously receives and consumes the benefits as the entity performs;
- the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced; or
- the entity's performance does not create an asset with an alternative use to the entity, and the entity has an enforceable right to payment for performance completed to date.

If control transfers **over time**, an entity selects a method to measure progress that is consistent with the objective of depicting its performance.

If control transfers at a **point in time**, the following are some indicators that an entity considers to determine when control has passed. The customer has:

- a present obligation to pay;
- physical possession;
- legal title;
- risks and rewards or ownership; and
- accepted the asset.

Customer options

Customer options may be accounted for as performance obligations, resulting in more revenue deferral than under legacy US GAAP.

Revenue is allocated to a customer option to acquire additional goods or services, and is deferred until (1) those future goods or services are transferred or (2) the option expires when it represents a material right. A material right exists if the customer is only able to obtain the option by entering into the sale agreement and the option provides the customer with the ability to obtain the additional goods or services at a price below stand-alone selling prices.

Licensing of intellectual property

The new standard includes a framework for determining whether there is a license of IP, and the category into which it falls.

As a result, the pattern of revenue recognition for licenses could differ from legacy US GAAP.

How an entity recognizes license revenue depends on the nature of the license. There are two categories of licenses of IP:

- **Functional IP.** IP is functional if the customer derives a substantial portion of the overall benefit from the IP's stand-alone functionality – e.g. software, biological compounds, films and television shows. Revenue is generally recognized at the point in time that control of the license transfers to the customer.
- **Symbolic IP.** IP is symbolic if it does not have significant stand-alone functionality, and substantially all of the customer's benefit is derived from its association with the licensor's ongoing activities – e.g. brands, trade names and franchise rights. Revenue is generally recognized over the license period using a measure of progress that reflects the licensor's progress toward completion of its performance obligation.

There is an exception to the general revenue model on variable consideration for sales- or usage-based royalties related to licenses of IP. Such a sales- or usage-based royalty is recognized as revenue at the later of:

- when the sales or usage occurs; or
- on the satisfaction or partial satisfaction of the performance obligation to which the royalty has been allocated.

Warranties

Warranties do not have to be separately priced to be accounted for as performance obligations.

Assurance-type warranties will generally continue to be accounted for under existing guidance – i.e. Topic 450 (contingencies). However, a warranty is accounted for as a performance obligation if it includes a service beyond assuring that the good complies with agreed-upon specifications. This could require some warranties to be separated between a service element (deferral of revenue, which is then recognized as the services are provided) and an assurance element (cost accrual at the time the good is transferred).

Principal vs. agent

The new standard changes the guidance used to evaluate whether an entity is a principal or an agent.

Credit risk is no longer an indicator that an entity is a principal.

An entity identifies each specified good or service to be transferred to the customer, and determines whether it is acting as a principal or agent for each one. In a contract to transfer multiple goods or services, an entity may be a principal for some goods and services and an agent for others.

An entity is a principal if it controls the specified good or service that is promised to the customer before it is transferred to the customer.

Indicators that an entity has obtained control of a good or service before it is transferred to the customer are having primary responsibility to provide specified goods or services, assuming inventory risk, and having discretion to establish prices for the specified goods or services.

Contract modifications

A general accounting framework provides most entities with more guidance in the new standard than under legacy US GAAP.

The new standard requires an entity to account for modifications either on a cumulative catch-up basis (when the additional goods or services are not distinct) or a prospective basis (when the additional goods or services are distinct).

If any additional distinct goods or services are not priced at their stand-alone selling prices, the remaining transaction price is required to be reallocated to all unsatisfied performance obligations, including those from the original contract.

Contract costs

More costs are expected to be capitalized under the new standard.

An entity cannot elect to expense or capitalize. Capitalization is required when the criteria are met.

The new standard provides guidance on the following costs related to a contract with a customer that are in the scope of the new standard:

- incremental costs to obtain a contract; and
- costs incurred in fulfilling a contract that are not in the scope of other guidance.

Incremental costs to obtain a contract with a customer (e.g. sales commissions) are required to be capitalized if an entity expects to recover those costs – unless the amortization period, which may include anticipated contracts or renewals, is less than 12 months.

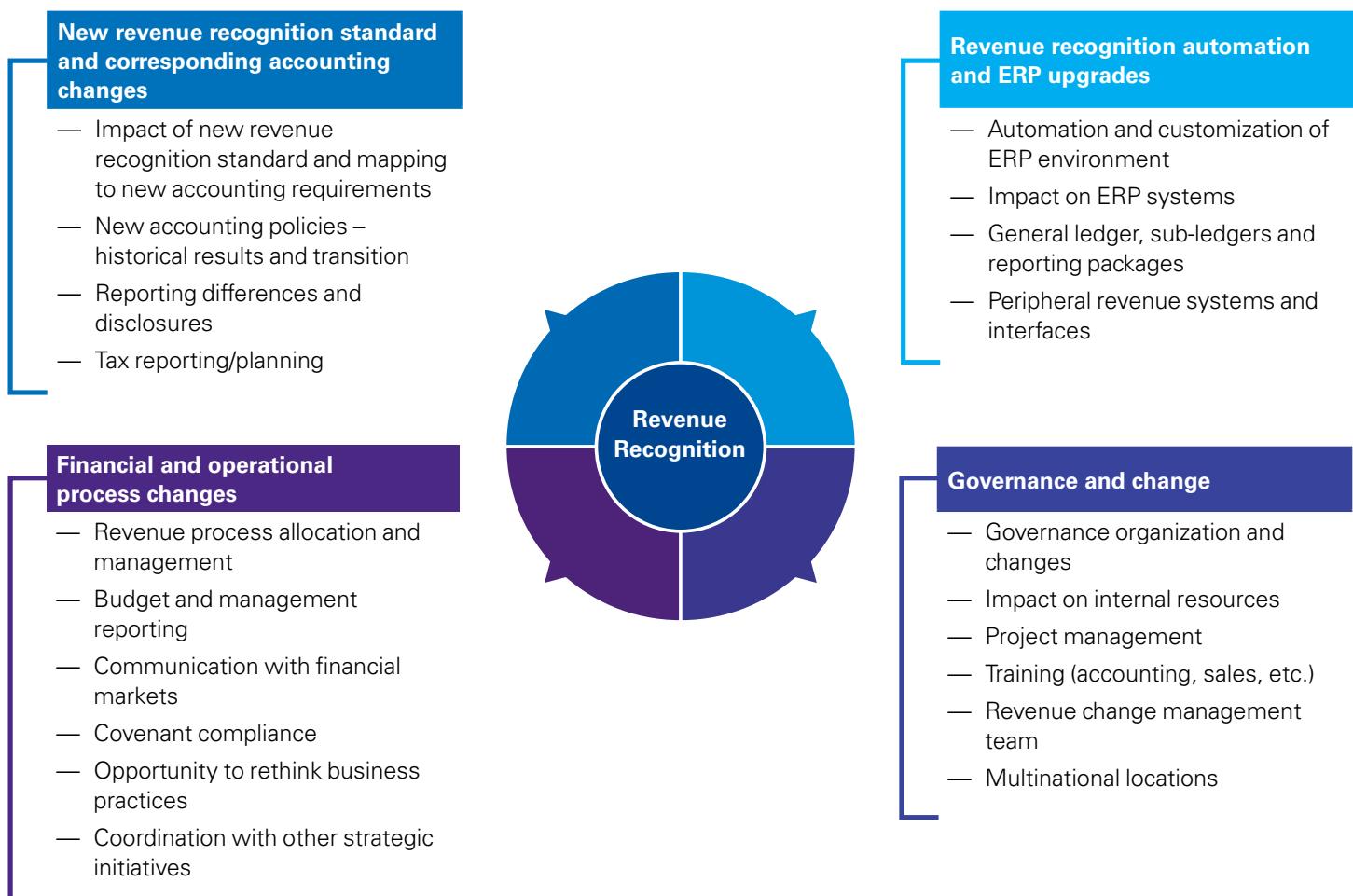
Fulfillment costs that are not in the scope of other guidance – e.g. inventory, intangibles, or property, plant, and equipment – are capitalized if the fulfillment costs:

- relate directly to an existing contract or specific anticipated contract;
- generate or enhance resources that will be used to satisfy performance obligations in the future; and
- are expected to be recovered.

An entity amortizes the assets recognized for the costs to obtain and fulfill a contract on a systematic basis, consistent with the pattern of transfer of the good or service to which the asset relates.

The impact on your organization

Implementation of the new standard is not just an accounting exercise.



As noted in the chart, the new standard could have far-reaching effects. The standard may not only change the amount and timing of revenue, but potentially requires changes in the core systems and processes used to account for revenue and certain costs. Entities may need to design and implement new internal controls or modify existing controls to address risk points resulting from new processes, judgments, estimates

and disclosures. The implementation of the new standard will involve a diverse group of parties (e.g. Tax, IT, Legal, Financial Planning, Investor Relations, etc.) and entities should have a governance structure in place to identify and manage the required change. For more information about implementation challenges and considerations, see chapter 14 of KPMG's [Revenue: Issues In-Depth](#).

KPMG Financial Reporting View



Insights for financial reporting professionals

As you evaluate the implications of new financial reporting standards on your company, KPMG Financial Reporting View is ready to inform your decision-making.

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FRV focuses on major new standards (including revenue recognition, leases and financial instruments) – and also covers existing US GAAP, IFRS, SEC matters, broad transactions and more.



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Insights for financial reporting professionals

Here are some of our resources dealing with revenue recognition under the new standard.

Handbook	Assists you in gaining an in-depth understanding of the new five-step revenue model by answering the questions that we are encountering in practice, providing examples to explain key concepts and highlighting the changes from legacy US GAAP.
Issues In-Depth	Provides you with an in-depth analysis of the new standard under both US GAAP <i>and</i> IFRS, and highlights the key differences in application of the new standard. Additionally, chapter 14 provides implementation considerations.
Illustrative disclosures	We show how one fictitious company has navigated the complexities of the revenue disclosure requirements.
Transition options	Assists you in identifying the optimal transition method.
Industry guidance	See our other industry guidance.

Contacts

KPMG is able to assist life sciences companies as they navigate the adoption of the new standard.

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