Accounting for outcome-based payment arrangements in the life sciences sector

US GAAP accounting considerations for outcome-based payment arrangements

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Introduction

The use of outcome-based payment arrangements in the life sciences sector is growing in many jurisdictions. In these arrangements, the consideration to which an entity is entitled depends upon an outcome (e.g., the performance or actual results of the entity's drug). In the US, outcome-based payment arrangements may provide an opportunity for a life sciences entity to increase patient access to innovative therapies and treatments, as well as to achieve overall sales expectations. However, they also present unique challenges. Operationally, outcome measures may be difficult to reasonably determine. Additional complications include the sourcing, administration and cost of data collection. Furthermore, parties responsible for paying for drugs (referred to as "payors" in this publication, which can include insurance companies and governmental organizations) are concerned about the duration of the agreement because it can be affected by the beneficiary's longevity in a health insurance plan and lack of portability of the terms of the arrangement. However, recent changes made by the Centers for Medicare & Medicaid Services to "Best Price" (BP) calculations, used to determine Medicare and Medicaid rebates, were designed to encourage the use of outcome-based arrangements to better reflect the value and effectiveness of a drug, and the industry expects to see an increase in these arrangements as a result.

Given the continued pricing pressure exerted by payors, the trend of employing innovative pricing strategies to gain drug acceptance will likely continue in the future. This publication discusses some of the accounting considerations for such arrangements when they are within the scope of Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*.[1] The accounting for outcome-based payment arrangements can be complex and is highly dependent on the specific facts and circumstances of each arrangement.

[1] For IFRS considerations, please refer to IFRS Accounting considerations for outcome-based payment arrangements. Available on ey.com.

Outcome-based payment arrangements

In outcome-based payment arrangements, the consideration to which an entity is entitled depends upon an outcome (e.g., the performance or actual results of the entity's drug). There are numerous ways to structure an outcome-based pricing arrangement. However, these generally fall into one of three categories:

- **Clinical efficacy risk sharing:** This refers to sharing the risk associated with the therapeutic performance of the product. If the drug fails to meet a clinically defined outcome, the payor will typically receive a refund from the manufacturer.
- **Cost-effective risk sharing:** This includes setting a target for cost effectiveness whereby, if the threshold is not met, typically the payor will receive a refund from the manufacturer. For example, a life sciences entity may lower the sales price of a drug in order to reflect similar pricing with a competing therapy.
- **Fixed budgets or price and volume agreements:** This refers to setting a budget based on utilization and/or price and can include provisions such as price, utilization or budget caps. For example, a payor may agree to cover a predetermined number of treatments, with the cost of any additional treatments borne by the manufacturer.

In order to avoid any unintended financial reporting consequences, life sciences entities should include members of the finance function early in the process of structuring an arrangement and consider proactively consulting with their financial accounting advisory contacts and independent auditors regarding the expected accounting treatment.

How we see it

While this publication focuses on some of the accounting implications of outcome-based payment arrangements, entities should consider a number of questions in addition to those addressed in this publication, including:

- When is an outcome-based pricing arrangement appropriate for the entity?
- From a business perspective, what considerations are needed in defining the performance measure and performance period?
- Does the entity have the infrastructure, processes and controls required to capture and manage data needed to track outcomes?
- Which party to the arrangement will be responsible for tracking outcomes?
- What are the tax implications?
- What compliance issues should be considered?

Scope

When assessing how to account for an outcome-based payment arrangement, the first step is to determine whether the arrangement is within the scope of ASC 606 or another topic such as ASC 460, Guarantees, or ASC 808, Collaborative Arrangements. Collaborative arrangements, for example, may or may not be outside the scope of ASC 606 based on whether the counterparty is a customer for a unit of account in the arrangement.[2] In the rest of this publication, we consider only those arrangements that are within the scope of ASC 606.

[2] Please refer to *EY Financial reporting developments: Revenue from contracts with customers (ASC 606)*, Section 2.3 Collaborative arrangements, for further discussion on this topic. Available on ey.com.

Overview of ASC 606

The core principle of ASC 606 is that an entity recognizes revenue at an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring promised goods or services to a customer. The principles in ASC 606 are applied using the following five steps:

1. Identify the contract(s) with a customer
2. Identify the performance obligation(s) in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligation(s) in the contract
5. Recognize revenue when (or as) the entity satisfies its performance obligation(s)[3]

Life sciences entities, when determining the accounting treatment for their contracts with customers, need to go through each of these five steps and consider all the specific requirements of ASC 606. This publication highlights only some of the key aspects when applying the five-step model to outcome-based payment arrangements.[4]

Identifying the contract with the customer

The model in ASC 606 applies to each contract with a customer. In many transactions, a customer is easily identifiable. However, in transactions involving multiple parties, it may be less clear which counterparties are customers of an entity.

Contracts may be written, oral or implied by an entity's customary business practices, but must be legally enforceable and meet specific criteria. The criteria are:

- Approval of the contract by all parties
- Identification of each party's rights in respect of goods and services to be transferred
- Identification of the associated payment terms
- The contract has commercial substance
- It is probable that the entity will collect substantially all of the consideration to which it expects to be entitled in exchange for the goods or services that will be transferred to the customer[5]

When considering the criterion for identified payment terms, it is important to note that the standard does not require that the transaction price be fixed or stated in the contract with the customer. Provided there will be an enforceable right to payment, and the contract contains sufficient information to enable the entity to estimate the transaction price, the contract would qualify for accounting under the ASC 606 model (assuming the remaining criteria have been met). Therefore, the fact that the amount of consideration depends upon an outcome (e.g., the performance or actual results of the entity's drug; a cost-effectiveness target; a price, utilization or budget cap) would not, in itself, preclude the arrangement from being identified as a contract with the customer under ASC 606.

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[3] ASC 606-10-05-4.

[4] Please refer to *Financial reporting developments: Revenue from contracts with customers (ASC 606)* for comprehensive guidance on applying the standard and *Technical line: How the new revenue standard affects life sciences entities* for further discussion on the application of ASC 606 to life sciences entities. Available on ey.com.

[5] ASC 606-10-25-1.

Determining the transaction price

The transaction price is based on the amount to which the entity expects to be entitled for transferring promised goods or services to a customer. This is meant to reflect the amount that the entity has rights to under the present contract. That is, the transaction price does not include estimates of consideration for future additional goods or services. However, if an entity has rights under the present contract to amounts that are to be paid by parties other than the customer (e.g., a payor), these amounts should be included in the transaction price.

In many cases, the transaction price is readily determinable because the entity receives payment when it transfers promised goods or services, and the price is fixed. Determining the transaction price is more challenging when the consideration is variable.

Consideration paid or payable by the entity to a customer also may affect the determination of the transaction price, regardless of whether the party receiving the consideration is a direct or indirect customer of the entity or a payor. This guidance also encompasses any consideration payable to any parties in the distribution chain for that contract. Under ASC 606, an entity accounts for consideration payable to a customer as a reduction of the transaction price unless the payment is in exchange for a distinct good or service that the customer transfers to the entity.

If consideration payable to a customer is accounted for as a reduction of the transaction price, an entity recognizes the reduction of revenue when (or as) the later of either of the following events occurs:

- The entity recognizes revenue for the transfer of the related goods or services to the customer.
- The entity pays or promises to pay the consideration. That promise might be implied by the entity's customary business practices.

However, to determine the appropriate timing of recognition of consideration payable to a customer, entities also need to consider the guidance on variable consideration, including the constraint. That guidance requires that all potential variable consideration (e.g. discounts or refunds for goods or services provided) be considered and reflected in the transaction price at inception and reassessed as the entity performs. In other words, if an entity has a history of providing this type of consideration to its customers (or other parties in the distribution chain), the guidance on estimating variable consideration would require that such amounts be considered in estimating the transaction price at the inception of the contract.

Distinguishing between variable consideration and customer options

For outcome-based arrangements within the scope of ASC 606 and that meet the ASC 606 contract criteria, an entity must determine whether the outcome-based feature represents variable consideration or a customer option.

If the payment terms of the arrangement provide for a rebate, discount or free products applied prospectively after a certain number of doses, we believe the rebate, discount or free products generally would be accounted for as a customer option rather than as variable consideration. This is because the consideration for the goods in the present contract is not contingent upon, or affected by, any future purchases, and the volume rebates, discounts or free products affect only the price of future (optional) purchases.

Conversely, we believe that, where the terms of the outcome-based payment arrangements are such that the prices for the products are adjusted retrospectively, such arrangements would give rise to variable consideration. This is because the final price of each product sold depends on the customer's total purchases subject to the rebate or discount program. That is, the consideration is contingent on the occurrence or nonoccurrence of future events.

Appropriately distinguishing between variable consideration and a customer option may require the use of judgment and is important because it affects the accounting for the contract at inception and throughout the life of the contract, as well as the required disclosures.

Variable consideration (and constraint)

As previously discussed, if the consideration promised in a contract includes a variable amount, an entity is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer at contract inception.[6] A life sciences entity is required to estimate variable consideration using either of the following methods, depending on which better predicts the amount of consideration to which it will be entitled:

- The "expected value" method: Using this method, a life sciences entity estimates the expected value of variable consideration using the sum of probability-weighted amounts in a range of possible amounts under the contract. To do this, the entity needs to identify the possible outcomes and the probabilities of those outcomes. This method may better predict expected consideration when an entity has a large number of contracts with similar characteristics or when an entity has a single contract with a large number of possible outcomes.
- The "most likely amount" method: In this method a life sciences entity estimates the amount of variable consideration using the single most likely amount in a range of possible consideration amounts. This method may be the better predictor when the entity expects to be entitled to one of two possible amounts.[7]

Life sciences entities need to consider all information (e.g., historical, current and forecast) that is reasonably available when applying these methods.

The second step in estimating variable consideration requires life sciences entities to apply a constraint to all variable consideration. That is, an entity is required to include in the transaction price some (or all) of an amount of variable consideration estimated in the first step, but only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.[8]

[6] ASC 606-10-32-5.

[7] ASC 606-10-32-8.

[8] ASC 606-10-32-11.

When developing a reliable estimate for outcomes or assessing the variable consideration constraint, a life sciences entity would need to consider a number of factors, including:

- Existence of commercial treatment data: Estimating probabilities for a specific outcome (i.e., a performance measure predetermined between an entity and a payor) may be challenging for a new drug, as performance information will generally be limited to clinical trial data. Generally, clinical trial data alone is not considered a sufficient basis for assessing the likelihood of achieving a performance measure. That is because the clinical data is often not representative, as clinical trials are generally conducted with a tightly controlled group. For example, only patients with certain symptoms or characteristics are allowed in the study or there is a tight control over ensuring that patients take the drug the right way. Furthermore, when using clinical data, an entity should assess whether factors, such as demographics and lifestyles of the patients in the clinical trial, are representative.
- Experience in other markets where the drug is sold: In cases where the drug is already marketed in other markets, entities may be able to leverage commercial treatment data from those markets in order to assess the likelihood of achieving a performance measure for the market in question. However, this will require entities to monitor the outcome data in those markets (including those where outcome-based arrangements may not currently exist). Entities should also consider whether the patient populations in those markets are representative of the patient population in the market where the outcome-based arrangement exists.
- Length of time for which outcome data is available: In general, the shorter the period of time for which the outcome data is available (whether from clinical trials or commercial experience), the more judgment will be required to assess the likelihood of achieving a performance measure.
- Whether the performance measure is based on an appropriately large population size: Generally, more judgment will be required to develop an estimate for a performance measure or assess the likelihood of its achievement based on results for an individual patient or small population of patients due to the inherent uncertainty about how an individual patient will respond to a drug.
- Objectivity of the performance measure: In general, the less objective the performance measure, the more judgment will be required to develop reliable estimates of outcomes or assess the likelihood of its achievement. For example, an outcome-based measure that is based on how much pain the patient feels on a scale from 1 to 10 is less objective than measuring blood sugar levels.
- Length of the performance period: Generally, the longer the required performance period, the more judgment will be required to develop reliable estimates of outcomes or assess the likelihood of its achievement.
- Monitoring of the drug being administered: The more monitoring there is of the drug being administered (e.g., to make sure the patients administer the drug in the proper frequency and amounts as prescribed by the health care personnel), the more reliable the measurement of the outcomes will be (as the measured outcomes might otherwise be significantly distorted).

When a life sciences entity determines that it cannot meet the probable threshold if it includes all of the variable consideration in the transaction price, the amount of variable consideration that must be included in the transaction price is reduced. The amount included in the transaction price is limited to the amount that, if subsequently reversed when the uncertainty associated with the variable consideration is resolved, would not result in a significant reversal of cumulative revenue recognized. Even when there is significant uncertainty about the ultimate outcome of a contract, a life sciences entity should not automatically default to constraining the estimate of variable consideration to zero.

If DrugCo, in the example below, determined that the available outcome data was sufficient to conclude that it is probable that no significant revenue reversal

Illustration 1: Clinical risk-sharing arrangement

DrugCo has a drug that treats a certain type of cancer. This cancer is generally incurable, but DrugCo's drug has been proven to increase life expectancy more than traditional therapies. The drug is initially administered over a five-treatment course; patients' tumor burdens are evaluated to determine whether patients are responsive, whereupon responding patients may need further treatments. For the purpose of these illustrations, assume that DrugCo sells its drug to a distributor, who then sells the drug to hospitals or other care facilities for administration to patients. DrugCo considers the distributor to be its customer. DrugCo also enters into arrangements with payors that may affect the ultimate transaction price.

Assume that DrugCo enters into an agreement with PayorCo in Market A, whereby DrugCo agrees to reimburse PayorCo the full cost of treatment for those patients whose tumor burden does not show certain predetermined results after the initial course of treatment (e.g., primary tumor stops growing and secondary metastatic tumors shrink). PayorCo agrees to continue paying for any necessary follow-on treatments for responding patients (i.e., those patients whose tumor burden achieved the predetermined results) under a separate follow-on agreement.

DrugCo has clinical trial data indicating that 80% of patients taking the drug have an increased life expectancy. However, in this case, the clinical trial data does not provide information directly related to evaluating success against the performance measure established with PayorCo and, thus, has limited predictive value for the purpose of estimating the transaction price. Historical commercial treatment data in markets outside of Market A has shown a 65% success rate for achieving the performance measure established with PayorCo.

The contractual price agreed to with the customer (before consideration of the arrangement with PayorCo) for the initial five-treatment course is $100,000, and DrugCo transfers control of 10 initial treatment courses (i.e., 50 doses) to the distributor, for a total contractual price of $1 million.

Accounting considerations

Since the cost of treatment is adjusted retrospectively, the arrangement would be accounted for as variable consideration. DrugCo assesses that the expected value method is the most appropriate due to a large number of patients and, thus, possible outcomes under the contract. The amount of the estimated variable consideration that DrugCo can include in the transaction price (which would include amounts received from the customer net of any amounts that may be repaid to PayorCo) is limited to the amount for which it is probable that a significant reversal of cumulative revenue for the contract will not occur.

would occur with respect to the estimated variable consideration of $650,000 ($1 million * 65%, i.e., the success rate achieved in other markets), it would be able to include this amount within the transaction price and would recognize it as revenue when (or as) it satisfies the related performance obligation. The remaining $350,000 would only be included in the transaction price if and when it becomes probable that a significant reversal of this amount will not occur, which may be when the uncertainty associated with this variable consideration is resolved.

The assessment of variable consideration estimates, and constraint may require significant judgment and are required to be updated each reporting period. The above factors are not intended to be all-inclusive, and the specific facts and circumstances of each arrangement must be considered.

Customer options for additional goods

In some outcome-based payment arrangements, life sciences entities provide the customer with the right to future purchases of additional drugs or treatments for free or at a reduced price. Under ASC 606, such an option gives rise to a separate performance obligation if the option provides a material right to the customer that it would not receive without entering into that contract.[9] If an option is a separate performance obligation, a portion of the transaction price is allocated to the option. Recognition of the allocated amount as revenue is deferred until the option is exercised or expires.[10]

A variation of the scenario in Illustration 1 above is shown in Illustration 2 below.

How we see it

Significant judgment may be required to determine whether a customer option represents a material right. Estimating the stand-alone selling price of an option that represents a material right can be challenging because those estimates may have limited underlying observable data.

Accordingly, it is important for entities to have robust processes to estimate stand-alone selling prices of options to be able to demonstrate the reasonableness of the calculations they make in estimating stand-alone selling prices.

Illustration 2: Fixed budget/price and volume agreements

Assume the same facts as in Illustration 1. However, the arrangement with the payor is different. In this scenario, DrugCo enters into an agreement with PayorCo in Market A whereby PayorCo agrees to pay DrugCo for the first five-treatment course, with the expectation that a patient's tumor burden would demonstrate certain predetermined results after this initial course of treatment. DrugCo has agreed to provide, at no cost to PayorCo, up to six additional necessary follow-on treatments if this expectation is met. The option expires two years after completing the initial five-treatment course.

In exchange for the initial five-treatment course, DrugCo is entitled to $100,000, which is similar to that charged by DrugCo to other payors in other markets.

Accounting considerations

The terms of the agreement include free treatments to be provided in the future if certain conditions are met, which are accounted for as a customer option to purchase additional goods. If the option for additional free-of-charge treatments represents a material right, it should be accounted for as a separate performance obligation. DrugCo would need to apply ASC 606 requirements to allocate a portion of the transaction price to the option and defer the recognition of that amount as revenue until the follow-on treatments are provided or the option expires.

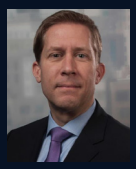
[9] ASC 606-10-55-42.

[10] For more information on accounting of customer options for additional goods and services refer to *EY Financial reporting developments: Revenue from contracts with customers (ASC 606)*, Sections 4.6 Customer options for additional goods or services, 6.1.5 Measurement of options that are separate performance obligations and 7.8 Recognizing revenue for customer options for additional goods and services. Available on ey.com.

Summary

As shown in Illustrations 1 and 2, the accounting for outcome-based arrangements can be judgmental and complex. Careful consideration of the facts and circumstances related to each arrangement will be necessary to determine the appropriate accounting treatment, as even relatively small variations in an arrangement's terms or the related fact pattern may lead to a different conclusion.

Contacts



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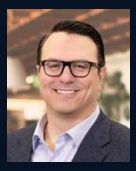

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